

103
**REINVENTING THE FEDERAL FOOD SAFETY
SYSTEM**

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Reinventing the Federal Food Safety...

HEARINGS

BEFORE THE

**HUMAN RESOURCES AND INTERGOVERNMENTAL
RELATIONS SUBCOMMITTEE**

AND

JOINT HEARING

BEFORE THE

**HUMAN RESOURCES AND INTERGOVERNMENTAL
RELATIONS SUBCOMMITTEE**

AND THE

**INFORMATION, JUSTICE, TRANSPORTATION, AND
AGRICULTURE SUBCOMMITTEE**

OF THE

COMMITTEE ON

GOVERNMENT OPERATIONS

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST AND SECOND SESSIONS

**NOVEMBER 4 AND 19, 1993; MAY 25; AND SEPTEMBER 28, 1994, HUMAN
RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE**

JUNE 16, 1994, JOINT HEARING

VOLUME 2—APPENDIX

Printed for the use of the Committee on Government Operations



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CONTENTS

Page

APPENDIXES—VOLUME 2

Appendix 1.—Additional statements submitted for the November 4, 1993, hearing record	1
Appendix 2.—Additional material for the November 4, 1993, hearing record ...	50
Appendix 3.—Additional material for the November 19, 1993, hearing record .	174
Appendix 4.—Additional statements submitted for the May 25, 1994, hearing record	334
Appendix 5.—Additional material for the May 25, 1994, hearing record	350
Appendix 6.—Additional statements for the June 16, 1994, hearing record	489
Appendix 7.—Additional material for the June 16, 1994, hearing record	494
Appendix 8.—Additional material for the September 28, 1994, hearing record	687

(III)

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APPENDIXES

APPENDIX 1.—ADDITIONAL STATEMENTS SUBMITTED FOR THE NOVEMBER 4, 1993, HEARING RECORD

FOUNDATION TO ELIMINATE
E.COLI OUTBREAKS
P.O. Box 3553
Seattle, Washington 98124

October 26, 1993

The Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
House Committee on Government Operations
B-372 Rayburn, HOB
Washington, D.C. 20515-6148

Dear Mr. Chairman,

It has been brought to our attention that there will be hearings to re-vamp the Federal Food Safety System in November.

Please consider including the following testimonies for the written statement of the records.

You may contact me at 1-800-88-ECOLI for any questions or comments.

Sincerely,

Diana Nole

Diana Nole, Secretary
Foundation to Eliminate E.Coli Outbreaks
529 S. 52nd Street
Tacoma, Washington 98408

Foundation to Eliminate E.Coli Outbreaks
 P.O. Box 3553
 Seattle, Washington 98124
 1-800-88-ECOLI

Who we are:

A non-profit foundation of families and friends of victims of E.Coli O157:H7 outbreaks and concerned people. We are not looking to place blame, but to seek solutions and offer educational information and support to those in need.

Why we formed:

In January, 1993, in Washington state alone over 600 people became ill. 144 were hospitalized, 30 experienced kidney failure and developed HUS, and three children and one adult died as a result of exposure to the E.Coli O157:H7 bacteria. After the outbreak a USDA Meat Inspector warned:

"I predict that you will see more cases of food poisoning, more people dying, more people getting sick from eating contaminated meat."

We will not let this happen.

OUR MISSION

To put a stop to E.Coli O157:H7 outbreaks through:

1. Education/Awareness

To seek the latest research on E.Coli related topics and provide information to the public, medical community, media, and the government that can bring about the end of E.Coli outbreaks.

2. Legislation

To promote legislation for mandatory testing and reporting of all E.Coli O157:H7 and HUS cases throughout the country.

To promote legislation to improve the meat inspection industry and focus it's attention on public health.

3. Support

To provide support for affected families in dealing with these devastating diseases. To provide information on long-term HUS research and support efforts to find a cure for these deadly diseases.

Hello, my name is Diana Nole.

I have written this testimony to tell you what can and does happen far too often when fecal contaminated, improperly prepared, ground meat is consumed.

My husband and I lost our only child, Michael James Nole, to the ravages of E.Coli 0157:H7 incited hemolytic uremic syndrome.

My son was born on December 9, 1990 a healthy 9lb 14 oz bundle of love.

He died 25 months, 13 days later. In 12 days, USDA approved, E.Coli 0157:H7 contaminated, undercooked hamburger, that was in a children's meal purchased at a fast food restaurant that my son consumed rapidly led to H.U.S. and eventually, his death.

All of the things my son went through were the most horrific things I have ever seen in my 8 years working in the medical field, and my most recent 2 years working in an Emergency Room.

My son had bouts of diarrhea, which rapidly became runny, painful and eventually bloody....and later all blood.

He was admitted to Mary Bridge Children's Hospital in Tacoma, Washington. I had no idea what was soon to follow.

The bloody diarrhea continued throughout the night, every 3-5 minutes with screams of pain and terror with each one. We went through a diaper with each one because the blood burned his skin.

In the morning, he was transferred to the pediatric I.C.U. unit. Unknown to us, there were already children there with E.Coli 0157:H7.

By this time his kidneys had shut down and he was becoming very lethargic, his abdomen began to swell to an unbelievable size. He had hemorrhoids and was unable to eat or urinate.

I remember the last time my husband and I saw our son responding and sitting up with our help. Due to his swollen tummy and tubes in his arms, he ate an orange popsicle and I kept trying to tell myself he was going to be okay.

Dialysis was needed and the decision was made to transport him to a children's hospital in Seattle that had the machines for this purpose.

Before they transported him I had asked to rock him in my arms in a chair next to his bed. With the help of 3 nurses and his physician, they carried him over to me with all of his tubes, IV's and other monitoring devices and set him in my arms.

Page 2

I rocked him and sang our favorite songs together. One of our favorites was "Jesus Loves Me". To this day, I cannot bear to hear this song.

This was the last time I held my baby in my arms.

He was transported to Children's Hospital in Seattle, I rode in the ambulance with him and two other transport nurses. We made the hour trip in 22 minutes.

When we arrived we were whisked to Pediatric ICU where we were moved into a room with another child. I did not know at the time that this other child had the same horrific HUS that my son was experiencing.

While they were setting up Michael in his bed, I went over to the little girl in the next bed. Her parents were out of the room and I wanted to say hello. As I approached her I noticed how recessed her eyes were, how pale her skin was and that she had many tubes and lines in her little body. I said "Hi, looks like we get to share a room with you, what is your name" She whispered in an airy voice "Brianne". This was Brianne Kiner.

As the days went on and chest tubes were inserted in my baby, more IV's and lines poked in and out, blood drawn, and many other procedures done, his condition worsened, as did Brianne's.

I met Briannes mom and dad, Suzanne and Rex. It was so indescribable to watch other parents go through this, we were sharing in something that words can not explain. But they know.

Dialysis began for us, and I was certain that this is all he needed to survive and pull through this. I was very mistaken.

Late one night, Brianne took a turn for the worse and she was whisked away to a private more 1 to 1 care room.

Michael had dialysis one or two times a day. There were so many other children arriving daily that needed dialysis that the machines were becoming very popular. Nurses, physicians and all other specialists were working around the clock, many sleeping at the hospital to provide the best possible care for our children.

As Michael's meds increased and tried to help his pains, things got even worse.

The physicians thought we might lose him at several different times, and several times we were rushed in to say our last good-byes and prayers. This was so very painful.

Page 3

As our family members started to arrive to kiss his cheek and stroke his golden hair and say prayers I just sat back in complete helplessness, thinking "I'm his mommy...why can't I fix this? Make everything better? Trade him places?" This was such a hopeless, powerless feeling.

After physicians noted he had red patches on his tummy, they thought something might have burst inside him. The suggestion was made to rush him into surgery to see if they could stop or identify the internal bleeding.

Papers were signed and we kissed him good-bye one more time in the hallway on his way to surgery.

I cannot remember how long it took.....1,2,3, hours, seemed like 2 days.

When he returned they said they "lost" him once during surgery but were able to revive him.

When we were allowed to go in to see him he had an incision from his neck to his groin area. This was so difficult to see.

He did not do well after this, he opened his eyes once, and we were able to see the blue of his eyes and barely a twinkle. I told him he was mommies big boy and that I would love him forever and someday would be with him forever in heaven. My husband and I spent several hours with him before he died. The nurses gave me a lock of his golden hair to cherish.

I left the hospital with his blanket, shoes, choo-choo train sweats I made him and a bag of toys.

I miss my big boy.

Diana Nole
529 S. 52nd Street
Tacoma, Washington 98408
10/93
TSTMNOLE.WPS

Foundation to Eliminate E.Coli Outbreaks
P.O. Box 3553
Seattle, Washington 98124
1-800-88-ECOLI

Hello,

My name is Michael Nole. I am with the Foundation to Eliminate E.Coli Outbreaks.

My son Michael James Nole was the first child that died at Seattle Children's Memorial Hospital, January 22, 1993.

Michael died from eating an undercooked cheeseburger contaminated with the deadly strain of bacterium E.Coli O157:H7 which rapidly developed into H.U.S., Hemolytic Uremic Syndrome.

It took 12 days for E.Coli & H.U.S. to kill our 2 year old son, while all my wife and I could do was watch helplessly, not being even able to explain to him what was happening.

Doctors can only provide case management and try to keep the patient comfortable.

It has been 8 months since we buried our son, and the only thing I have seen the U.S.D.A. do is mandate safe handling labeling requirements for meat and poultry products.

Don't get me wrong, this is a good first step, but I credit the Beyond Beef Coalition which got the government to require the labels as part of the settlement of a lawsuit. I also think the U.S.D.A. should have required the labels to be more specific. It should tell consumers to cook meat until it is no longer pink in the middle and that the juices should run clear.

It sickens my wife and I to learn that more children have died from E.Coli O157:H7 & H.U.S. due to tainted beef since we lost our son in January.

When is the U.S.D.A. going to get serious about this problem and start taking the proper steps in solving it?

We must have changes based on scientific facts

We need slower line speeds

Fast accurate on-line testing

Page 2

Comprehensive traceback systems

Safe and sanitary conditions in slaughter houses

We want more meat inspectors

Nationwide reporting of E.Coli 0157:H7 and H.U.S.

We need to educate the public on safe food handling

It is no safer today to eat hamburger than it was the day my son did and died 12 days later.

What is it going to take before something is done about the way the U.S.D.A. inspects meat.

I ask you Secretary Espy, is it going to take the loss of your child or your friends child before I see some changes?

I hope none of you ever have to go through what my wife and I and especially my son, Michael, went through.

My wife and I are members of Foundation to Eliminate E.Coli Outbreaks. Through the foundation we plan to push for changes in the way meat is inspected and educate the public on safe food handling. Our foundation also provides a toll free (800-88-ECOLI) phone number which people can call for concerns on E.Coli 0157:H7 (H.U.S.), safe food handling and we also offer a support group.

We offer a monthly newsletter free of charge which lists our goals, foundation progress and the latest information on prevention. We also offer a 30 page medical report we will mail out upon request for a \$5 donation fee for copying and postage.

It is through the foundation we feel we can make some good come out of Michael's death.

By educating the public on E.Coli & H.U.S. we hope we will give them the knowledge to prevent such a disaster from happening to them.

Thank You.

Michael James Nole, President
Foundation to Eliminate E.Coli Outbreakss
P.O. Box 3553
Seattle, Washington 98124
800-88-ECOLI

8/93

The Devastating Effect that E.Coli 0157:H7 Had on Our Family

By: Dorothy and Joseph Dolan

My name is Dorothy Dolan. I have 2 daughters, Mary 4, and Aundrea 3. They both became severely ill after eating contaminated hamburgers from a local Jack in the Box restaurant on January 3rd of this year. On January 8th Mary started having painful diarrhea, that was orange in color, every hour. The next day the pain and frequency got much worst. She became very lethargic and with each diarrhea movement came screams of pain. Mary was taken to the hospital emergency room for treatment. After several hours of tests she was transferred to Children's Hospital and Medical Center in Seattle. The doctors at Children's informed us that they suspected that Mary was suffering from E.Coli 0157:H7. The next day Aundrea was admitted to Children's as well, suffering from the same symptoms.

My husband and I spent the next two days carrying our daughters to the bathroom. Listening to the moans and groans during the nights and the screams during the day. While the bloody diarrhea continued, Mary pleaded "Mommy please take the pain away!", our daughters continued to slip further and further into this terrible illness. They had no appetite and they became weak and irritable. On January 12th Mary woke up with a bloody nose and urinated very bloody urine. While on the toilet, Mary looked up at me with her big blue eyes and asked "MOMMY - AM I GOING TO DIE?".

My worst fears were coming true. I was seeing my daughters get sicker and sicker. The doctor informed me that Mary had developed Hemolytic Uremic Syndrome (HUS) and was going downhill. They looked at Aundrea and said that she was following the same course. I remember thinking that just 5 days ago I had two healthy precocious girls and now I'm faced with loosing both of them. Then the nephrologist came in and spoke about the possibility of blood transfusions, stating that may last between 2 to 3 weeks or a lifetime if necessary. That same day Mary's blood tests showed a platelet count of 6,000 whereas the normal level is 150 to 250 thousand. We were told that Mary needed a platelet transfusion.

Being a nurse I started to worry about her exposure to HIV and hepatitis. As Mary was taken further and further into this medical nightmare, Aundrea started to show signs of slipping further as well. Aundrea awoke the next morning with a bloody nose and had blood in her urine. I refused to believe she was going "DownHill". "How could this be?" I prayed to God -- Then, calling family in from New York for support, My husband and I started to discuss the fact that we were loosing our girls.

We did not have much time for discussion because the doctors soon came in and told us that if Mary did not start eating she would have to have a feeding tube placed down her throat to provide nutrition. Mary tried eating but could not keep anything down. After throwing up two times she started to complain that her eyes were hurting and to "shut up" because our voices hurt her ears. She then screamed that her head hurt and screamed to take the pain away. I felt out of control - my daughter was out of control - and my sister in law had to calm me down while the nurse tried to calm down Mary. Finally Mary calmed down and fell asleep.

I was sipping soup in the next bed when the next sound my husband and I heard was Mary screaming that her head hurt. My husband ran to her to comfort her. He cuddled next to her and hugged her tight, but the screams kept coming. She then started screaming MAMMA, MAMMA!. I ran to her and held her in my arms. I called her name and held her tight, but she couldn't focus her eyes at me, they stared fixated out of the left corner of her eye. She kept calling form me as if she didn't know I was holding her. My husband rushed out to call for the nurse and doctor STAT. While we were waiting what seemed like hours, Mary was slowly getting worse. Her mouth was closing, her left side was not moving and her voice was slowly slurring NURSE! NURSE!. The Doctors did not know what was happening. They rushed her off to do a CAT-SCAN of her head.

My husband went with her while I had to get out and walk and try and rationalize that she was okay. While in the CAT-SCAN room, while Mary was strapped to the table, my husband watched helplessly as Mary vomited once again - this time however she was unable to help herself because of the restraints that were placed on her. My husband screamed for the doctor and nurse and they rushed back into the room and removed the vomit from her mouth.

After the CAT-SCAN Mary returned to her room with my husband and the doctors with the diagnosis of a right parietal stroke. As she returned to her room my husband stayed with her holding her left hand as she lied lifelessly in bed. He closed his eyes for a moment to try and escape the nightmare for a moment when he noticed her left hand beginning to shake. He opened his eyes and looked at Mary's face and noticed her tongue sticking out of her mouth while her eyes stared endlessly at his face. At that point her whole body began to shake as the doctors rushed into the room. The doctors began treating her for a seizure. My husband held her hand through out the entire episode, which seemed to last about 10 minutes. One of the medications that was given to Mary to help with the seizure made her sleepy and she was finally able to rest.

At that point my mother arrived from New York. I cried and held her as tight as I could and told her Mary had a stroke and a seizure and was very sick. My mother cried and went over to Mary. Mary was sleeping and hadn't moved since the seizure. My mother called to her and blessed her with holy water. Mary miraculously moved her left side and moaned. We were then told the next few hours were going to be the critical ones. Mary could have more strokes and seizures and

we could not know how she would neurologically end up. The decision was made to move her to a intensive care unit.

Aundrea's lab values had stabilized and the Dr.'s cautiously stated that Aundrea maybe taking a turn for the better but she would have to be closely watched.

When we all arrived in the I.C.U. a new group of Dr's approached us. They stated that Mary's stroke and seizure were serious complications and the prognosis was poor. He continued to say that the toxin that is produced by E.Coli 0157:H7 could continue to spread to other organs, the liver, pancreas, lungs, and heart even her teeth could fall out. She could even die. I told him no more. I couldn't bare to hear that my baby's body could be taken over and torn apart from this toxin. My daughter lied there asleep while the Dr.'s and nurses put more tubes in her, iv's placed in both arms and legs, oxygen placed to help her breath. Monitors assessing every vital sign. Her little arms tied to the bed so she wouldn't knock out her iv lines.

We still at this point didn't know how much damage the stroke had done. I never thought I would have to see my daughter like this. A stroke at 4 years old and being so very close to death. All we could do was pray. My husband spent the night running between Aundrea's room and Mary's I.C.U. room. Mary made it through the night without any more strokes or seizures. The nephrologists at that point approached us and said that Mary's kidneys were failing and they recommended dialysis. With dialysis also came possible complications such as bleeding, cerebral hemorrhage, etc. I remember thinking just do anything that will help her. She received her second blood transfusion then she received her first and only dialysis treatment. The treatment was scheduled to last 3 hours but had to be cut short because of the irritability of Mary due to the pain of the treatment. Throughout all of the pain medication that she was on, the treatment was still very painful for her.

The next day she continued to urinate into a diaper. Her kidneys were not working 100% but they were at least working and the Dr's didn't feel she would need another dialysis treatment. Mary was very irritable during her I.C.U. stay. With the irritability Mary's blood pressure continued to rise. The Dr's had to keep her drugged up with narcotics to keep her calm so she wouldn't have another stroke. To this point we still hadn't seen her open her eyes or hear her speak.

The next couple of days were agonizing wondering if she'll take a turn for the worse and die. We waited to if she'll ever stabilize. We waited with anxious breath every four to six hours for her lab results because they would determine if she was getting better or worse. In the meantime we got to hold her with all her lines attached. She didn't wake, she just moaned. It was like holding a sack of potatoes, she was so limp and had no tone to her body. Her feet were swollen, her right side of her face was swollen because her kidneys weren't working well. She hadn't eaten for over a week and they had to start artificial feedings called hyperalimentation. While in bed she refused to lie still. She tried to sit up but had no strength. As soon as she started to get up her body would collapse and

she would fall back to the mattress, my husband and I reaching out to catch her to make sure that she did not hurt herself. She looked like a boxer in the 15th round of a title fight who was hanging on for dear life.

Luckily the next day the Dr.'s approached us and said not to get too excited but Mary's lab results were stabilizing and she may be recovering. Yes, our prayers were answered and it looked like we would have a long road to recovery. IV lines were being removed, she was slowly opening her eyes and we could start feeding her ice cream. Her left side was weak and her speech was minimal and slurred. When we tried to sit her up she couldn't hold her head up and we had to hold it up for her.

We moved her from the I.C.U. to her regular room the same day Aundrea was discharged. Our work was cut out for us. We had to get her to eat, to learn to sit up to hold her head up, to walk, and to use the bathroom again. We got physical therapy, speech therapy, and occupational therapy to evaluate Mary and to start treatment. The Dr's told us we could take her home soon and continue therapy on an outpatient basis. The day finally came when Mary could go home. She was weak. She couldn't take two steps without falling. Her body was skin and bones with a protruding abdomen. She looked as if she had been through the battle of her life, which she had.

Six months have passed. Mary's physical therapy is done. Her blood pressure is higher than normal. Her kidney's are functioning well. She has a higher chance of a seizure than the rest of us. Mary's speech is still slow at times and at times stutters. No one is sure how the stroke has effected her cognitive abilities. Aundrea is still getting routine urine tests.

Not a day goes by that I don't think about what has happened.

Not a day goes by that I don't worry about the blood transfusions, their kidney functions, and the possible long term effects.

Not a day goes by that I don't hear about another child sick from E.Coli and hemolytic uremic syndrome. I cry and feel sick to think another child and family has to go through what we had been through.

We cannot continue to let our children suffer and die from something that can and should be prevented. From something that is stamped U.S.D.A. approved.

Please listen to all these stories and learn about the devastating effects of E.Coli and hemolytic uremic syndrome.

Help us prevent this nightmare from happening to another innocent child and family.

Fred & Annalesa Thomas
 Daughter: Phalese Christine Thomas (age 3)
 4730 N.E. 15th Street
 Tacoma, Washington 98422

January 16, 1997 began a nightmare for our family.

As we watched helplessly while our two year old daughter went through pain impossible to describe.

She had been having blood, stools which her doctors had been checking on. Yet E.Coli O157:H7 was not being looked for at this point. Even though she was having diarrhea the week before the 15th, we were not overly concerned.

The night of the 15th she seemed to be in much more pain. By early morning I knew she had much more than "just the flu". I rushed her to the doctor, she laid almost lifeless on the seat next to me lifting her head only, to say "owee owee Mommie". She was admitted to Mary Bridge Hospital. My husband and I spent the next seven days at her bedside praying we would not lose our little girl.

It was four days before we put together that a hamburger my husband ate was the most likely cause for our daughters illness.

Although she never tested positive for E.Coli O157:H7, we are sure that this was what she had suffered and that she only tested negative because so much time had past before she was tested.

She did not go into Hemolytic Uremic Syndrome, however, she experienced temporary kidney failure.

She also had to undergo two exploratory surgeries after she was released from the hospital the first time, to determine the damage to her colon. This was especially traumatic for her because just the sight of the hospital sent her into hysterics.

As a result of the E.Coli she has developed Colitis which really restricts her diet and causes her to have bouts of bloody stool.

She might eventually loose all or part of her colon.

Because of her diet, she remains a very small child for her age.

Page 2

The whole experience has caused her to regress. She was becoming very baby like and she had to be returned to a bottle for both security, as well as added nourishment. Likewise we had to return her to diapers because her ability to ask to go potty seemed to be gone.

She is making slow progress, however, she is easily frightened.

All we can do as parents is help her with today, and pray for her tomorrow.

10/93

THMSTST.WPS

Statement of
J. Patrick Boyle
President and CEO, American Meat Institute

House Committee on Government Operations
Subcommittee on Human Resources and
Intergovernmental Relations
November 4, 1993

Much has been made in recent months of the disparity in government food inspection programs. For example, for every dollar spent to inspect meat and poultry by the Food Safety and Inspection Service, only 12 cents is spent to inspect the remainder of the food supply by the Food and Drug Administration. For every FDA food inspector, the Food Safety and Inspection Service employs eight meat and poultry inspectors. And for every plant inspected by FSIS, FDA inspects three.

In sum, FSIS inspects one-third the food plants with eight times the budget and eight times the staff. More than one million taxpayer dollars are spent every day to inspect meat and poultry products.

Meanwhile, CDC statistics show that only one-fourth of foodborne illness outbreaks result from the products FSIS inspects. Furthermore, those statistics indicate that 77 percent of foodborne illness outbreaks are triggered by mistakes made in commercial kitchens -- a link in the food chain monitored to varying degrees by state and county health departments, with oversight from FDA.

Vice President Gore's "Reinventing Government" report highlights some of the regulatory problems and inconsistencies that result from the current inspection programs at FDA and FSIS. It observes that meat and poultry products must be inspected daily, while shellfish, which have the same risk of causing foodborne illness, are not required to be federally inspected at all.

With respect to enforcement, the report points out that if FDA finds unsanitary conditions or contaminated products, compliance is usually voluntary because the agency lacks FSIS's power to close plants, withhold inspection or detain suspected or known contaminated products. And if one agency refers a problem to another, follow up is at best slow and at worst ignored.

The report also notes that there are no fewer than 21 agencies engaged in research on food safety, often duplicating each others efforts, and that we not progressing fast enough in understanding and over-coming life-threatening illnesses.

The report correctly points out that USDA relies primarily on inspection by touch, sight and smell. It calls for more modern and reliable methods based on science.

Under the report's recommendations, the FDA would handle all food safety regulations and inspection, spanning the work of the many different agencies now involved. The new FDA would have the power to require all food processing plants to identify the danger points in their processes in which safety inspections would focus. Where and how inspections are carried out, not the number or frequency of inspections, would determine the efficiency of the system.

The FDA would also develop a rigorous, scientifically-based system for conducting inspections.

The report concludes by stating that we should employ the full power of modern technology to detect the presence of microbes, giving Americans the best possible protection. Whenever possible, reporting should be automated so that high risk foods and high risk food processors can be identified quickly. Enforcement powers should be uniform for all types of foods with incentives built in to reward business with strong safety records.

Whether or not the recommendations from Vice President Gore's report are acted on with respect to consolidating inspection at FDA - this report could provide a blueprint for modernizing and improving our approach to food safety and food inspection. At a minimum, it should also serve as a wake-up-call to USDA's Food Safety and Inspection Service, encouraging the agency to accelerate the process of inspection modernization, proceed with their Hazard Analysis and Critical Control Point (HACCP) initiative, and shift their emphasis from inspection to prevention.

Preventing foodborne illness is only one component of federal food inspection programs, but it is the most important part. The entire debate over "Reinventing the Federal Food Safety System" centers not on where our programs are headquartered nor who has jurisdiction, but on preventing public health hazards.

If we truly intend to move forward with a more effective Federal food safety system, then all affected parties must agree on one point: let science drive the issues and the reform initiatives. Only science can break the gridlock.

For too long, labor, consumer groups, government and industry have deadlocked over issues having nothing to do with public health. Entire food safety bills have been derailed over such things as whistleblower protection, which has nothing to do

with protecting consumers' health.

NAS Report on Meat and Poultry Inspection

If the recommendations in Vice President Gore's report on reinventing government sound familiar, it is because they are not dissimilar from the recommendations cited in a 1985 report from the National Academy of Sciences and from similar recommendations from industry groups, including the American Meat Institute.

In its 1985 study on meat and poultry inspection, NAS recommended that USDA's Food Safety and Inspection Service develop a Hazard Analysis and Critical Control Point, or HACCP, approach to monitoring food safety.

The NAS Study generally concluded that:

- Consumers have a high level of confidence that meat and poultry products are safe and wholesome.
- That new programs and procedures instituted by FSIS in slaughter and processing areas are unlikely to reduce those aspects related to public health protection, however, such changes need to be well-defined in terms of relevant public health issues.
- And that there is a positive willingness to change at USDA/FSIS in order to provide short and long range policy management systems that accommodate new technologies.

In order to effectively implement these conclusion, the NAS study recommended that:

- Personnel skills within FSIS management should reflect an interdisciplinary concept such that not one profession (discipline) is dominant.
- That policies and programs should more adequately reflect what is and is not "critical" in terms of public health risk.
- And that these programs should clearly focus on identifying the source and risk of potential problems and establishment of management systems for prevention at the source.

NAS encouraged FSIS to apply HACCP concepts to each and every step in plant operations and all types of enterprises involved in production, processing, storage and ultimate utilization of meat and poultry products.

NAS said hazards should clearly be defined as those associated with public health risk. By focusing on hazards and control points related to public health concerns over those which

are aesthetic and unrelated to public health, FSIS could attain the highest degree of public health protection within available resources.

Continuous inspection is not needed to ensure food safety in meat and poultry processing plants in which critical control points have been identified and are being controlled and monitored by a qualified staff. The NAS report stressed that the identification of critical control points is the very foundation for constructing any modern quality control system.

One problem with traditional meat and poultry inspection is that an inordinate amount of time and effort is spent on relatively minor deficiencies which have no relation to public health risk or economic adulteration. This wastes precious resources and puts public health at risk.

Using HACCP principals both within companies and in the Federal meat and poultry inspection system, both FSIS and the industry could direct available resources to the most important problem areas.

Inspection Must Change to Focus on Preventing Pathogens

The 1985 NAS report also stated that "The inspection system is not designed to detect human pathogens unless they produce an observable lesion (in animals). This therefore raises a fundamental questions as to what the current inspection procedures provide for the public."

I would like to address the microbial hazards today's inspection system is not designed to detect. First, because they are the subject of much misinformation and misunderstanding. Second, because they pose the more serious public health hazard.

The slaughter and butchering of carcasses is intended to be carried out under sanitary conditions, but they are not surgically sterile. Animals and birds may sometimes harbor microbes on exterior or interior surfaces (as do humans).

But the presence of microbes does not necessarily indicate health risk. Indeed, any unprocessed food is virtually certain to carry some kind of microbiological contaminant, including fresh fruits and vegetables, milk, eggs, and grains.

Human illness occurs only if the microbe reaches the human body in numbers adequate to cause infections, and at a time when biological defense mechanisms are unable to respond to the challenge. With proper slaughter, processing and distribution; careful food handling in homes and restaurants; and adequate cooking, the microbial risks of meat and poultry to the consumer are close to zero.

Conditions are not always perfect, of course, and one may ask whether today's traditional "organoleptic" meat and poultry inspection (by sight, touch and smell) can adequately protect the public. The answer is no, not to any appreciable degree.

The microbial contamination that leads to human health risk is not sufficient to make slaughtered birds or animals visibly ill, and in most cases makes up only a tiny fraction of the total microbial burden. That burden as a whole is simply not generally detectable by organoleptic inspection.

This should not surprise us. The human body, too, is covered with countless microorganisms, some of which are capable of causing disease if they get past the skin. But those microorganisms cannot be seen, of felt, or smelled--and they usually cause no trouble.

Shortcomings of Traditional Meat and Poultry Inspection

In summary, traditional organoleptic inspection of freshly slaughtered meat and poultry has almost nothing to do with the protection of human health.

I believe that the focus on animal disease detection and the lack of focus on human pathogens is the most significant flaw in USDA's inspection philosophy and has been the root cause of much of the negative publicity and lack of public confidence that finally resulted in the Vice President's recommendation to eliminate FSIS as a separate agency.

Simply moving FSIS to another agency, however, is not the solution. What we need is not reorganization. What we need is a new system that is science driven.

Last February Agriculture Secretary Mike Espy outlined a two track program to modernize the inspection system and reduce the incidence of pathogens in raw meat and poultry. This pathogen reduction program is consistent with the NAS recommendations and the philosophy outlined in the Vice Presidents' report. Industry supports most of Secretary Espy's recommendations.

We supported in principle two components of the FSIS plan - zero tolerance for visible defects on beef carcasses and safe food handling labels for raw meat and poultry. Unfortunately, due to flawed implementation, these efforts have resulted in millions of dollars in unnecessary cost.

Suggestions for Improvement

In my view, the key for FSIS is to rely more on scientific principles as the agency implements the NAS recommendations and as it responds to sudden events such as the E. coli crisis.

FSIS should move quickly and decisively to implement HACCP and provide an aggressive HACCP training program for inspectors. The recent decision to postpone a proposed rule on HACCP erodes FSIS's credibility.

If FDA successfully implements HACCP for seafood and other FDA regulated products, and FSIS is unsuccessful in implementing a HACCP rule for meat and poultry, consumers and industry will suffer and the pressure to consolidate inspection at FDA will increase. Such consolidation is a non-solution that deflects attention and resources from the real problem.

In addition to successfully implementing HACCP into inspection reform initiatives, FSIS must effectively communicate improvements to the public. Public confidence is vital to the success of government programs. FSIS must restore public confidence in meat and poultry inspection the way FDA has worked to restore public confidence in its regulation of the food and drug industries.

Finally, and most importantly, both USDA and we in industry must deliver on our commitment to make meat and poultry products safer.

How Industry Can Help

AMI and the AMI Foundation have already developed many technologies to control pathogens and are looking to establish more. New technology using mildly acidic carcass sprays and decontamination procedures offers practical means to reduce pathogens.

Other methods of reducing pathogens in meat packing plants include antimicrobial dips, such as the trisodium phosphate recently approved for poultry; more sanitary hide removal, using equipment or chemical treatments to reduce contamination, and the possibility of a final pathogen reducing treatment such as cooking or irradiation.

We also need to look to the farm and livestock production as critical parts of the process where pathogens can be minimized or destroyed. In the poultry industry, for example, growers are trying to breed Salmonella resistant chicks. Probiotics may also be useful in controlling harmful microorganisms in live animals.

As we look further down the food chain through distribution, retailing and handling, there are critical points in the process, including safe storage temperatures to prevent microbial growth, and observing safe cooking temperatures.

This Administration has stated its commitment to change the way government works -- including the way meat and poultry are

inspected. The meat and poultry industry supports constructive change -- but not change simply for the sake of change.

We must move forward in developing science-based initiatives, including HACCP, to improve the safety of meat and poultry products.

11/93

For Record



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Statement of the
NATIONAL PORK PRODUCERS COUNCIL
Before the
Subcommittee on Human Resources and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
on
"Reinventing the Federal Food Safety System--
USDA's Progress in Reforming Meat and Poultry Inspection"

November 4, 1993**Submitted by:**

Karl Johnson
President
National Pork Producers Council
Mankato, Minnesota

National Headquarters

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The Other
White Meat.

Mr. Chairman and Members of the Subcommittee:

On behalf of the National Pork Producers Council, I am pleased to have this opportunity to share our views on "Reinventing the Federal Food Safety System - U.S. Department of Agriculture's (USDA) Progress in Reforming Meat and Poultry Inspection." The National Pork Producers Council (NPPC) represents approximately 85,000 pork producers through 45 state affiliates. Our members account for more than 90 percent of this nation's pork production.

It is essential that we as pork producers meet consumer expectations for safe, wholesome pork products. U.S. pork producers have long understood the importance of producing a product in which our domestic and international consumers could have the utmost confidence. We believe USDA's Food Safety and Inspection Service (FSIS) on-going reputation as a modern, science-based agency is of critical importance. We are operating in a global market and our system for food safety must be acknowledged by our current and potential export market customers as at least equivalent to theirs, if not the best in the world.

Progress in Reform of Meat and Poultry Inspection Programs

We are encouraged by the resolve of Secretary of Agriculture Mike Espy, Assistant Secretary for Marketing and Inspection Services Eugene Branstool and Administrator of the Food Safety and Inspection Service Russell Cross in addressing the complex area of reforming the current meat and poultry inspection system. Their "two-track approach" will afford us the opportunity to make significant advances in implementing a truly science-based meat and poultry inspection system.

Substantial progress has been made in recent months in gathering information that will assist our efforts to make meaningful changes in the current inspection system. FSIS has held six public hearings allowing all constituents the opportunity to comment on FSIS's Strategic Plan and Pathogen Reduction Program. In addition, both documents were open for comment through the Federal Register. The "World Congress on Meat and Poultry Inspection" held in October also allowed other countries to discuss their ideas for improvements in meat and poultry inspection.

The "Conference on Regulatory Programs of the Future" affords the opportunity for all constituents to again review the current progress and provide suggestions for the continued development of the new system. In addition, USDA's upcoming Hazard Analysis and Critical Control Point (HACCP) roundtable will provide an opportunity for experts to discuss the actual design and implementation of this approach to meat and poultry inspection.

Moreover, FSIS has instituted a Risk Analysis Program and obtained research authority that will be critical to directing research on high priority areas for the agency. The development of rapid detection tests for the presence of potential pathogens is one of the tools that will aid meat packers and processors in implementing and verifying their HACCP systems. FSIS has published their criteria for these types of tests recently in the Federal Register. To provide better insight into the public health aspects of foodborne illness prevention and detection, FSIS will be stationing a representative at the Centers for Disease Control and Prevention as well as developing a Public Health Program.

From our perspective, these are extremely positive, necessary steps in developing a risk-based, scientifically sound meat and poultry inspection system.

Current Food Safety System

There is no question that the routine detection of potential pathogens on raw meat or poultry products is beyond the scope of the present inspection system. The system currently in use was designed to be an organoleptic inspection that detected abnormalities that are now less common in animal agriculture today. The current system does a good job with antemortem inspection of only allowing healthy animals to enter the food chain. The post-mortem inspection functions to detect abnormalities of public health significance. However, FSIS has recognized that additional changes and enhancements are necessary to modernize the current system to one based on potential risks and current scientific technology.

Optimal Federal Food Safety System

The optimal food safety inspection system should be based on the best science available and a prioritization of the public health risks. Baseline microbiological studies are a critical step to determine the potential problems and identify the most likely critical control points.

HACCP should be the centerpiece of any program designed to modernize the U.S. meat inspection system. Controlling, monitoring and verifying processing systems is clearly more reliable and better able to ensure the safety of a product than reliance on end-point testing. There clearly needs to be appropriate flexibility to concentrate resources where potential public health problems exist. FSIS needs to verify that HACCP plans are being followed.

Research will continue to be a key component of a food safety system to allow continuous improvements to be made. Much more needs to be known about the epidemiology of potential human pathogens on-farm and throughout the food chain. At the same time, we must also strive to be early adopters of technological advances that will enhance food safety.

It would appear that the Animal Plant and Health Inspection Service (APHIS) should receive statutory authority, responsibility and resources to work on-farm with agricultural producers as more information becomes available about preharvest food safety techniques. APHIS has the on-farm background and through other programs has developed working relationships with farmers.

In addition, public education needs to be part of any system. Educational programs for all segments of the food chain on their responsibilities and role in maintaining the safety of the food supply is fundamental.

We believe there are insufficient resources to monitor for foodborne illness, to conduct epidemiological investigations of suspected foodborne outbreaks, and to collect and distribute timely reports to key participants in the food chain. This information is not only necessary to provide feedback to the stakeholders with responsibility for implementing an improved meat inspection system, but to prioritize where scarce

government resources should be directed in the future.

USDA as Lead Agency In Meat and Poultry Inspection

For several reasons, we support the continuation of USDA serving as the lead agency on meat and poultry inspection. USDA is currently implementing a number of new progressive food safety approaches and programs that will improve our nation's system of meat inspection. Such efforts should not be delayed or disrupted by an unnecessary movement or transfer of functions from one location to another.

In addition, with the emphasis on approaching food safety with a "farm to table" approach, USDA has the experience and the tools to work most effectively with everyone from the farmer to the consumer to ensure the safety and wholesomeness of our meat and poultry products.

We do not believe any other agency in the federal government is more capable of making the necessary modifications in our meat inspection system than USDA's Food Safety and Inspection Service. USDA is truly in the best position to verify the integrity and safety of our meat and poultry supply throughout the continuum of the food chain. The same is true for seafood inspection, with USDA in the best position to handle this federal program of inspection.

Conclusion

The current public attention on food safety concerns provides us with a tremendous opportunity to make significant advances in implementing a truly science-based meat and poultry inspection system. NPPC appreciates the opportunities we have had to participate in the development of strategic plans and programs to address food safety concerns. Pork producers are ready to do their part to address their responsibilities in providing a safe and wholesome product to consumers.



AMERICAN VETERINARY MEDICAL ASSOCIATION

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November 16, 1993

The Honorable Edolphus Towns, Chairman
 Subcommittee on Human Resources
 and Intergovernmental Relations
 Committee on Government Operations
 2157 Rayburn House Office Building
 Washington, DC 20515-6143

Dear Mr. Chairman:

I am pleased to provide you with the attached statement for inclusion in the written hearing record of the November 4 hearing on "Reinventing the Federal Food Safety System -- USDA's Progress in Reforming Meat and Poultry Inspection."

Veterinary medicine is uniquely situated to contribute to this policy debate, embodying expertise along the entire spectrum from farm to fork, including vast experience and knowledge in the areas of animal and human health. If we may be of further assistance to you or your subcommittee staff, please contact Senior Policy Specialist Marcia Brody in our Governmental Relations Division at (202)789-0007. The veterinary medical profession stands ready to assist however it can.

Thank you for this opportunity to contribute these thoughts.

Sincerely,

Leon H. Russell

Leon H. Russell, DVM, PhD
 President

Reinventing the Federal Food Safety System
Statement of the American Veterinary Medical Association
November, 1993

On behalf of its more than 54,000 members, the American Veterinary Medical Association is pleased to contribute to the hearing record on the issue of food safety and USDA's progress in reforming meat and poultry inspection. Veterinary medicine has a several hundred year history of contributions to this issue and is the only profession concerned with both animal and human health that is involved in the full spectrum of food safety -- from the conception of the animal through consumption of the food products by humans. For this reason, veterinary medicine is and has been in a pivotal position to play a key role in improving the safety and quality of foods of animal origin.

Some of the major points contained in our statement include:

- ◆ Food safety programs should be based on scientifically sound principles of Hazard Analysis Critical Control Points (HACCP).
- ◆ The Food Safety and Inspection Service's Strategic Plan and Pathogen Reduction Program are a good start, but require additional focus and definition.
- ◆ Food safety efforts must be in place along the entire continuum from production to consumption.
- ◆ The problem of microbial contamination of food products requires different solutions than the problems of chemical residues, parasitic infestations, neoplasms, tumors and physical defects.
- ◆ The detection and control of microbial hazards must not take place at the expense of protection against chemical contaminants, lesions, abscesses and other abnormalities.
- ◆ The public health value of post-mortem, organoleptic inspection of animal carcasses should not be trivialized.
- ◆ An effective federal program must be an integrated effort that cooperatively coordinates with state and industry programs.
- ◆ Education efforts at the wholesale, foodservice, retail and consumer levels are appropriate first steps to pursue and will result in cost-effective improvements in food safety.

- ◆ Many of the precursors for pre-harvest food safety improvements are already in place and programs should be developed jointly with veterinarians, producers and state animal health authorities.
 - ◆ The American Veterinary Medical Association is dedicated to assuring that foods of animal origin are wholesome in nature and free of harmful chemical, parasitic, microbiological or pharmaceutical contaminants.
 - ◆ AVMA promotes responsible animal production to increase the safety and quality of animal products from healthy animals and is committed to pursuing appropriate educational, legislative and regulatory measures to meet these goals.
-

To be effective, food safety programs must be based on sound scientific principles and established principles of public health -- not driven by popular misconceptions and hasty political reactions to potentially misinformed public pressure. Analysis of true risks to public health and effective strategies to counter those risks at their critical control points provide the only feasible option for long-term effective policy. The program must also be realistic -- achievable within standard, affordable production and processing practices.

The AVMA applauds the general concepts expressed in the FSIS Strategic Plan and accompanying Pathogen Reduction Program that were released in May, 1993. We believe that this comprehensive campaign has great promise, but will require additional focus and definition in order to realize its full potential.

As the federal government moves forward in addressing food safety, it is important to keep in mind that each class of contaminants is unique and requires a different approach. Problems posed by microbial contamination and methods to control it are significantly different from those presented by chemical residues and parasitic infestations. Chemical contamination requires control points at the preharvest stage to detect and eliminate the contamination prior to slaughter. Similarly, most parasites can be detected and eliminated from the live animal through the judicious use of medications, which are, in turn, eliminated from the body prior to slaughter.

Bacteria, on the other hand, are ubiquitous in nature. One can attempt to eliminate pathogenic organisms, or to reduce them to inconsequential levels, but there remains the constant danger of recontamination and regrowth as a result of improper handling or storage. Even small numbers of microbes can rapidly increase when foods are not handled properly.

One deficiency of the USDA Pathogen Reduction Program is its scope. It does not address all

of the strategies for pathogenic risks along the entire chain from farm to fork. Instead, it seems to focus all microbial controls back to the production level. Simply focusing on minimizing microbial contamination at production fails to recognize the importance of minimizing the probability of later contamination and microbial growth through the assurance of proper handling and storage procedures.

Likewise, although we support USDA's efforts to develop improved technology to detect and prevent microbial contamination, we believe it must not be done at the expense of thorough organoleptic examination and testing for chemical residues. We know of no way other than organoleptic examination to detect tumors, parasitic lesions, foreign body abscesses and similar abnormalities. The food safety program must provide a comprehensive evaluation to assure the wholesomeness of the food product and its freedom from all types of contamination. The Pathogen Reduction Program is an ambitious undertaking of broad scope that, for technical, budget and political reasons, is unlikely to be implemented in a short time. We believe a sequenced implementation on a priority basis will achieve the greatest effect in the shortest period.

From a pragmatic standpoint, we believe that addressing consumer awareness and food service and retail activities offer one of the best areas for short-term gains in food safety. Consumers must be made aware that food is not a sterile product and that the potential for contamination always exists. Improper handling, storage at temperatures conducive to bacterial growth and incomplete cooking magnify those risks and increase the probability of foodborne illness. The AVMA applauds the efforts of USDA and Secretary Espy to expedite the use of safe handling and cooking labels and leaflets for meat and poultry.

Proper handling, storage and preparation throughout the food chain can prevent a large segment of the foodborne illness problem. Wholesalers, transporters, and retailers must be trained in and adhere to proper methods. Consumers must be knowledgeable about the food products purchased and make sure they are properly handled, stored and prepared prior to consumption. Food handlers in stores and restaurants must receive adequate training in food safety and sanitation.

A major concern about food safety regulation today is the fragmentation of the effort among scattered (and often competing) federal agencies and departments. According to the General Accounting Office, 12 federal agencies administer as many as 35 different laws directed at food safety and quality assurance. The inevitable problems of territorial disputes, finger-pointing and gaps in statutory authority for needed action are a major hindrance to effectiveness and efficiency, working to the detriment of the public that is supposed to be protected. The American public needs an integrated food safety regulatory program directed by a single agency or with clearly defined, cooperative responsibilities shared among participating federal agencies,

working under a shared leadership. The integrated federal component must work cooperatively with state and local governments and with industry and health professionals in a common effort with shared goals and objectives to serve the public's best interest.

The food safety initiative or agency must be managed by people who understand the problems of food quality assurance from the commercial, as well as consumer, viewpoints. It should be managed by people who have both academic knowledge and field experience in food production, inspection and regulation, so that they are able to see the broad picture and balance issues and options in a holistic framework.

An effective food safety program must also incorporate the 27 state meat inspection programs, which were not mentioned in the FSIS Strategic Plan. These programs are currently responsible for inspecting more than 3000 meat and poultry plants and provide half of the funding for the programs in more than half of the states. The leadership of these state programs must be included in the federal planning and decisionmaking process, or the states may not continue to fund their programs, which would in turn place a significantly increased financial burden on the federal treasury.

Many of the basic requirements for enhancing pre-harvest food safety and pathogen reduction are already in place or could be developed based upon existing models. Animal identification and trace-back mechanisms could be vastly improved simply by requiring FSIS inspectors to collect all of the identifying information that accompanies an animal (such as ear tags or other devices, rather than backtags only), until systems such as microchip identification become available.

The federal government should also draw upon and encourage programs such as state and industry quality assurance programs, which are based on cooperative efforts between producers and veterinarians. These programs, which are actively pursued in the dairy, beef, poultry and pork industries, have already proven effective in residue prevention and food quality assurance. They should be encouraged as cost-effective, affordable and acceptable models for future efforts.

Public misunderstanding of the current food safety program is widespread, and reaches to the highest levels of government, as evidenced by Vice President Gore's disparaging remarks about meat and poultry inspection in a television interview. Careful organoleptic inspection can identify most areas of abnormal tissue and provides an excellent opportunity to scientifically screen each carcass to detect signs of illness that affect the safety or quality of the meat. The Vice President's failure to recognize the importance of organoleptic inspection signifies a failure of current food safety regulators to educate fellow officials about their programs and the principles upon which they are built.

The AVMA is committed to working with producers, federal and state regulatory agencies, and consumer groups to define and implement a comprehensive, coordinated and effective food safety program. We look forward to working with the Congress, the Administration, state and local officials, private and consumer interests to collectively pursue appropriate educational, legislative and regulatory measures to meet these goals.

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November 17, 1993

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
U.S. House of Representatives
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

Members of the Safe Food Coalition (SFC) appreciate your invitation to appear before the Human Resources and Intergovernmental Relations Subcommittee on November 4, 1993 to present our views on USDA's longstanding failure to reform meat and poultry inspection to adequately protect public health.

We also appreciate the opportunity to respond to the charge, made by the National Cattlemen's Association, that the SFC has impeded USDA's attempts to reform meat and poultry inspection. The charge is untrue. We believe it arose from the Cattlemen's dismay that, after several years in which consumers and public health experts were excluded from all decisionmaking at USDA, Secretary Espy and Assistant Secretary Branstool have met with us, heard our concerns, and allowed consumers, as well as industry representatives, to comment on the proposed Hazard Analysis and Critical Control Point (HACCP) system in an organized fashion before the Department arrives at its position on this program.

In opening the process, the Secretary and Assistant Secretary have reversed a position taken by the Department during the past several years when USDA officials refused to allow consumer representatives to participate in the development of the HACCP program. Assistant Secretary Branstool has told us he believes that an open decisionmaking process on HACCP will lead to a better program.

We believe Secretary Espy and Assistant Secretary Branstool have done the right thing. As citizens and taxpayers, we have a right to petition our government and to make known our views about what constitutes an adequate meat and poultry inspection system. In fact, it is our view that government officials have an obligation to hear and consider our concerns. In any case, Messrs. Espy and Branstool have accorded our views no more consideration

Chairman Towns
November 17, 1993
Page 2

than has always been granted to the National Cattlemen's Association.

In order to make the record clear, I am including a chronology of our discussions with the Assistant Secretary and copies of the memoranda circulated to other members of the SFC to keep them abreast of our discussions with the Department.

The SFC believes the HACCP system of process control holds promise for improving food safety and reducing human illness. We have so stated on a number of occasions. Our concern about the role and structure of the system arises from the fact that USDA intends to make HACCP a major element of the meat and poultry inspection system. Meat and poultry inspection are paid for by tax dollars and the U.S. government warrants that inspected products are "wholesome." Since this is a public, taxpayer supported activity presumably conducted in order to protect public health, we assert that the public has an immutable right to review the data on which the inspection system is to be based and to judge whether the program is adequate to protect public health.

Since 1989, we have consistently sought the information necessary to determine if the HACCP system envisioned by FSIS will make food cleaner, safer and less likely to cause foodborne illness. We have tried to participate actively in the development of HACCP. However, USDA refused us any meaningful or constructive role in the process. The Department rejected our requests to participate in the meetings where government and industry conferred and agreed upon critical control points and the shape of the HACCP programs. Our representatives were required to sit silently in the back of the room while these discussions took place. Further, there are no consumer representatives in the main outside group advising FSIS on the structure of its HACCP program, the National Advisory Committee on Microbiological Criteria.

Although FSIS officials occasionally met with us to "seek our views" on HACCP, they told us the restrictions of the rulemaking process made it impossible for them to give us any detail on how they intended to structure the program or to explain any of their reasoning until publication of a proposed rule. In short, they sought our views without giving us specifics on which to comment.

In recent months the closed door started to open. In August 1993, we submitted a paper to Secretary Espy asking for data and a discussion of the details of HACCP.¹ We asked USDA to provide the

¹Safe Food Coalition, "Reinventing Meat and Poultry Inspection: Building a Public Health Based Program," August 17, 1993.

Chairman Towns
November 17, 1993
Page 3

public with data that demonstrate the effectiveness of HACCP as envisioned by USDA and to provide an opportunity for public discussion before USDA made final decisions and published its proposed HACCP plan in the Federal Register. (Although the Department would publish a "proposal" and seek comment on it, it is clear that a "proposed" regulation represents the Department's preferred position and has the allegiance of its staff. A final FSIS regulation does not often vary substantially from the proposal.) In a meeting with members of our Coalition on August 24, Assistant Secretary Branstool agreed to consider our request.

On August 30, 1993 Assistant Secretary Branstool called me and said USDA thought a period of public discussion before the HACCP proposal was issued would be a good idea. At Mr. Branstool's request, Tom Devine of the Government Accountability Project, Jerry Kuester of the Center for Science in the Public Interest and I met with the Assistant Secretary and other USDA officials on September 1, 1993. The USDA officials said they thought it would be a good idea to pursue our suggestion of a detailed and structured discussion of the Department's HACCP plan before it was published as a proposed rule. There was general agreement that a negotiated rulemaking was too lengthy and complex, but that we could use some elements of the negotiated rulemaking process to help shape a better HACCP program. All those present agreed that this process would have two salutary benefits: it would result in a better proposal and, because it provided an opportunity to recognize and deal with problems before the fact, could speed publication of a final rule.

On September 2, 1993, Patricia Stolfa of FSIS provided me with a draft copy of a Federal Register notice announcing a "HACCP Roundtable Discussion," which described how the meeting would be structured. On September 22, Ms. Stolfa forwarded a final draft and asked for comments from the SFC by September 27. We provided these on September 27. The September 22 draft stated that the HACCP Roundtable would be held on December 2-3, 1993.

However, when no notice had appeared in the Federal Register by October 21, my staff associate called FSIS to ask when we could expect the notice. She was informed that FSIS staff did not know. She called every couple of days for approximately two weeks. When no notice had appeared by the third week in October, I called USDA and spoke to Deputy Assistant Secretary Patricia Jensen. She told me the notice was still under review. I expressed concern about the delay since it was going to make it difficult to complete the planning steps we had discussed December 2. (These steps are outlined in the attached memorandum dated September 1). To my knowledge the notice still has not been published in the Federal Register. The SFC requested the forum. We are eager to have it occur. We feel strongly that the planning process is essential to

Chairman Towns
November 17, 1993
Page 4

making the discussion productive. It is surprising that anyone could interpret these events as an attempt by the SFC to delay the HACCP Roundtable.

You also asked me to address the impact of the SFC's suggestions for improving HACCP, detailed on pages 12-15 of our testimony, on the timeframe for USDA's development and implementation of a HACCP system. We included some time estimates for what we believe is a reasonable period to conduct some of the activities. We suggested six to nine months for the National Academy of Sciences (NAS) to conduct pilot tests of the HACCP system and six to twelve months for a full examination of all the pertinent issues by the various constituencies of the inspection system.

It is difficult for us to estimate the time required for the other portions. If the Department organized itself to gather the data expeditiously, it might complete the work quickly. If the Department had started back in 1985 as to gather the data recommended by NAS, the studies would have been completed long ago. We want an adequate and workable HACCP system that improves public health protection. We are prepared to do everything we can to advance that goal expeditiously. The ultimate period of time required is not ours to control.

Sincerely,


Carol Tucker Foreman

Enclosures

SAFE FOOD COALITION

1155 21st Street, NW, Suite 1000; Washington, DC 20036 (202) 822-8060

MEMORANDUM

TO: SAFE FOOD COALITION

FROM: FOREMAN, KUESTER, DEVINE

DATE: SEPTEMBER 1, 1993

RE: MEETING WITH USDA STAFF RE: HACCP

As per our agreement, Tom, Jerry and Carol met with USDA officials today to discuss ways to improve the USDA decisionmaking with regard to HACCP. USDA officials present were: Asst. Sec. Branstool, Deputy Asst. Secs. Patricia Jensen and Ken Clayton, FSIS Administrator Russell Cross, Asst. to Admin. Patricia Stolfi and Associate General Counsel John Goulden.

This meeting arose from our request last week that USDA "open up the process" by publishing the HACCP program either as an Advance Notice of Proposed Rulemaking or in some other fashion that would permit open discussion of the details prior to a proposed regulation.

The goal of the SFC proposal is to help USDA devise a better system for assuring that meat and poultry are cleaner, safer and less likely to cause foodborne illness.

USDA officials said today they were prepared to drop the draft proposed regulation and to engage in an open process with consumers, labor (inspectors) and the industry.

We discussed several ways in which to accomplish this and came to general agreement on the following:

1. Each of the affected groups (consumers, industry, inspectors union, USDA) will appoint a small number of people to represent the affected group as part of a planning committee to work on key issues and

structure of a facilitated meeting. The planning committee will work with the facilitator.

2. The representatives will decide on a number of "key issues." We used ten as the magic number but it could be a few more or less.

3. USDA will prepare papers on the issues. These papers may reflect USDA's position in some cases. Others will be options papers. Groups will be free to prepare their own papers on the issues. All papers will be collected and distributed to interested parties in advance of the meetings.

4. There will be a one or two day public meeting to discuss the issues.

"Participants" in the meeting, those who will sit around the table to actually try to come to some agreement or consensus on the issues, will be limited to a set number of people, equally divided among and chosen by the four affected groups. (The number of participants will be decided by the planning committee, but the number 25 was mentioned several times.)

5. After the meeting FSIS will draft proposed regulations which will go through the usual notice and comment rulemaking.

No one is committed to supporting the rules. The hope is that the open process will reduce the number of issues in conflict and perhaps introduce new possibilities for resolving continuing conflicts.

Some additional points:

1. Tom pressed hard for USDA to take a "leadership" position on issues that are mandatory for our support but on which the industry has been intransigent to date. He mentioned especially Branstool's favorable comments about whistleblowers, and some comment by Dr. Cross on "right to know."

The USDA participants did not agree to do this, but they did not decline, nor disagree with the necessity to avoid an impasse on these issues.

2. It was agreed that, if another foodborne illness outbreak should occur during this process, consumer groups would not attack USDA for delaying implementation of HACCP and USDA would not attack public interest advocates for seeking delay.

SFC members would not attack USDA for being slower than FDA in implementing HACCP.

- 3 -

SFC members remain free to argue that USDA should implement the improvements we advocate in the present system.

3. The timing was left open, but Stolfa said it would take four to five weeks for USDA to draft the papers after the issues were decided. If we start immediately: take three weeks to choose the planning committee, three weeks to decide the key issues, four-five weeks for USDA to write papers, four weeks for group papers, and three weeks to circulate papers before the meeting, the process may take five to six months.

Next Steps:

SFC members need to agree to this general process. USDA will clear it with industry and inspector's union leaders.

Please call any of us for information and let Carol know what your views are.

SAFE FOOD COALITION

1155 21st Street, NW, Suite 1000; Washington, DC 20036 (202) 822-6060

MEMORANDUM

TO: SAFE FOOD COALITION MEMBERS

FROM: CAROL TUCKER FOREMAN, HEATHER
KLINKHAMER

DATE: SEPTEMBER 16, 1993

RE: SFC MEETING, SEPTEMBER 17, 1993

I have just received word from USDA that they do not yet have any further information about details of how they propose to structure the "Roundtable Discussion on HACCP." They will have a proposal for us to respond to, but not until mid-week next week.

We have a regularly scheduled SFC meeting for Friday, September 24 and I suggest that we wait and have our strategy session on how to respond to their proposal at that time.

**Please let us know as soon as possible if you agree with
rescheduling the meeting until next Friday when we will have the USDA
proposal.**

I ran into Russell Cross earlier this week and he told me that the Broiler Council, Turkey Federation, two trade associations of small companies and the Cattlemen are inclined to participate. The American Meat Institute has declined but may reconsider now that the others are in.

September 27, 1993

MEMORANDUM

TO: PAT STOLFA

FROM: CAROL TUCKER FOREMAN
SAFE FOOD COALITION

RE: COMMENTS ON DRAFT NOTICE FOR HACCP ROUND
TABLE

The Safe Food Coalition met last Friday to discuss the draft outlining the structure of the HACCP Round Table Discussion. The following comments reflect the views of the members of the Safe Food Coalition.

We have several major concerns:

COMPOSITION OF ROUND TABLE PARTICIPANT GROUPS

1. The constituent groups have been established in a manner that provides a disproportionate number of seats at the table to individuals who are associated with the regulated industry and a minimum number of seats to representatives of the public interest community.

FSIS has identified seven groups: Meat and Poultry Trade Associations, Producer Organizations, Consumer Groups, Plants, Scientific Community, Employee Representatives, and Federal/state governments. Each group will have three representatives "at the table." FSIS also proposes that "persons who believe that some affected interest is not adequately they may request Round Table membership."

We do not understand the difference between the interests or composition of "Trade Associations" and "Plants." "Plants," in this context, are regulated corporations. The "Trade Associations" involved are

composed of regulated corporations. The effect this grouping is to give members of the regulated industry two sets of representatives.

We assume that the "Producer Organizations" category includes such groups as the National Pork Producers and National Cattlemen's Association. These groups are not regulated entities under the Meat Inspection Act and are not covered by the HACCP regulations FSIS has been considering. Therefore, we fail to understand why they are included in this discussion. We realize that, in the future, the law may be changed to give FSIS some regulatory authority to go back to the farm gate. However, that will not be part of the discussion at this stage and we suggest that this is not an appropriate group to include.

2. The titles for some groups are so general it is impossible to determine who will determine the representatives of the group.

We agree that members of the constituent groups should determine their representatives. In some cases, such as the Trade Associations, Employee Representatives or Consumers, the groups are reasonably well defined. Further, you have made provision for including individuals who may feel they have been unjustifiably left out of a particular category.

However, two of the categories, "Scientific Community" and "Federal/State Government" are very broad and we would like to know who you view as the representative group to choose delegates from these categories and how the representatives will be chosen.

In our view, the "Scientific Community" should include more than representatives of the agricultural research establishment. Further, the Safe Food Coalition believes it would be inappropriate to have the "Scientific Community" category include a preponderance of representatives who are affiliated with trade associations, regulated corporations, and the agricultural research community.

We raise this concern because the membership of the National Advisory Committee on Microbiological Criteria for Foods includes a number of individuals whose laboratories work for the industry and individuals who are employed by the meat and poultry industry as consultants. It would be best if the "Scientific Community" category could be assumed to include individuals whose expertise and orientation is human health and safety. We request that the Scientific Community group include representatives of the NAS Food and Nutrition Board, preferably either FNB staff who worked on or members of the committees that drafted the 1985 and 1987 studies on meat and poultry inspection.

We have a similar problem with the "Federal and State Governments" category. We assume this group will be structured to include more than representatives of USDA and state departments of agriculture. Once again, we are troubled by the model presented by the NACMCF. There are no representatives of state health or consumer protection agencies on that committee. We urge that the "Federal/State Government" category include representatives from state health departments and consumer protection agencies, as well as representatives from the Food and Drug Administration and the Centers for Disease Control.

3. We believe two additional categories should be added to the list: Additional categories that should be included in order to assure both balance and the coverage of essential fields of expertise. The categories should be:

"PUBLIC HEALTH AND HUMAN MEDICAL COMMUNITY"

Meat and poultry inspection is a public health activity. Although we believe human health experts must be included in the "Scientific Community" and "Federal/State Government" categories, we believe "Public Health and Human Medicine" is a community whose expertise warrants a separate category. Whereas the "Scientific Community" might include bench researchers in human health and the "Federal/State Government" category should include human health experts from state or city health departments and the CDC, we believe this category should be composed of individuals who represent those whose expertise is in the actual practice of human medicine and development of public health policy.

"WHISTLEBLOWERS"

Some of the most important information about difficulties in the present meat and poultry inspection system has come from whistleblower inspectors. These individuals represent an interest that is separate from that of employee representatives. The whistleblower inspectors have demonstrated that their greatest concern is not with the prerogatives of inspectors in respect to the employer organization. They are often at odds with the Agency. Their goal is the effective implementation of inspection to protect public health, even at the risk of their own advancement. We believe they bring a unique perspective.

We are eager to work cooperatively with USDA in this endeavor and believe you are making an honest effort to structure an appropriate meeting. To advance that goal it will be necessary to have some reasonably balanced representation of views at the table. The Round Table represents

an opportunity for USDA/FSIS to reach beyond its usual consultative community and we urge you to take full advantage of it.

ISSUE PAPERS

Safe Food Coalition representatives left the meeting with Assistant Secretary Branstool and FSIS officials with the understanding that the planning group would agree on a set of issues, that FSIS would draft issue papers and the groups could then comment on those.

Further, our earlier discussion indicated that, where FSIS has a position on an issue, it would indicate that position in the paper and would let us know what other options staff considered and rejected. There is no reference to that part of the process in this paper and we believe it is essential to making it as effective as possible.

In discussing the Round Table, some FSIS staff have described it as "getting more input." It is our understanding that the major goal is to identify the key issues, for FSIS to let us know in more detail the Agency's specific positions on those issues, to test those positions, and to examine whether the Agency and the constituent groups are able to come to some agreement, or at least diminish the differences between us, on them.

DATES FOR THE ROUND TABLE

We believe there should be some flexibility about the ultimate date of the Round Table, but early December seems reasonable unless there is a substantial delay in reaching agreement on process and issues.

GENERAL TONE OF THE NOTICE

The notice includes the statement, "This meeting is not a forum for posturing presentations that will draw media attention, but rather is envisioned as a substantive opportunity to assist the Agency in devising the best rule..."

The Safe Food Coalition checked with Miss Manners who told us she would be happier with the notice if it did not suggest the Agency believes its constituent groups have bad table manners.

FOREMAN & HEIDEPRIEM, INC.

Suite 1000
1155 21st Street, N.W.
Washington, D.C. 20036


Carol Tucker Foreman
Nikki Heidepriem
Diane E. Thompson

(202) 822-8060
FAX (202) 822-9088

September 29, 1993

MEMORANDUM

TO: Pat Stolfa

FROM: Carol Tucker Foreman 
Safe Food Coalition

RE: Additional Comment on Draft Notice for HACCP Round Table

In my previous memorandum, I outlined the Safe Food Coalition's concerns about the composition of round table participant groups. As mentioned, we feel that USDA can strike a better balance between the number of industry and public representatives proposed to participate in the discussion. In addition to the two categories suggested in the previous memo, "Public Health and Human Medical Community" and "Whistleblowers," I suggest that "Families and Victims of Foodborne Illness" be included.

This constituency can bring a unique perspective to the discussion. They have experienced the results of an inadequate inspection system first hand.

Final Draft

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

Hazard Analysis and Critical Control Point (HACCP)
Round Table

AGENCY: Food Safety and Inspection Service, USDA

ACTION: Notice

SUMMARY: Secretary Espy announced in late May, 1993, that he was giving the Food Safety and Inspection Service 90 days to present him with a proposed regulation for making the Hazard Analysis and Critical Control Point (HACCP) system of process control mandatory in all the nation's meat and poultry establishments. Recently, the Agency determined that it would be beneficial to allow all constituent groups greater access to the deliberative process prior to publishing a proposed regulation. Therefore, the Agency announces a HACCP Round Table meeting to be held on December 2 and 3, 1993, in Washington, D.C. The Agency views this Round Table as an opportunity to bring the legitimate concerns of all constituents to a meeting which would allow free and frank discussion, prior to a proposed regulation. This meeting is not a forum for posturing presentations that will draw media attention, but rather is envisioned as a substantive opportunity to assist the Agency in devising the best rule for implementing a mandatory HACCP system of production in all meat and poultry plants. This notice outlines the Round Table process, and requests that the constituent groups identified below select their own representatives for both a Steering Committee and the Round Table. Furthermore, this Notice offers the opportunity for persons who believe that some affected interest is not adequately represented to request participation as a participant at the Round Table.

DATES: Each identified constituent group must provide, within 14 days of the publication of this Notice, the names of three representatives for the Round Table, and one name for the Steering Committee.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Manis, Director, Import Inspection Division, International Programs, Food Safety and Inspection Service, 14th and Independence Avenue, SW., Washington, DC 20250 (202) 720-2952.

SUPPLEMENTARY INFORMATION: The Round Table meeting will be facilitated by a neutral third party employed by the Agency. The facilitator will provide a transcript of the meeting, as well as a final report which summarizes the positions of all the participants. The facilitator will seek the full participation of all the participants, and will strive for consensus where possible. Whether or not consensus is reached, the facilitator will ensure that all identified issues are addressed by the Round

Table participants.

The Round Table will be open to the public, including the media. Issue papers will be prepared in advance of the session by the participants and will be publicly available. The Agency is open to a consideration of all issues, except the question of HACCP becoming a mandatory system. All other issues surrounding a HACCP regulation are considered as not finally decided at the time that this Round Table process occurs. In order to keep the process manageable, the maximum number of Round Table participants will be 25.

The Agency has identified the following list of constituents:

- Meat and Poultry Trade Associations
- Producer Organizations
- Consumers Groups
- Plants
- Scientific Community
- Employee representatives
- Fed/State governments

Each party will select three actual representatives to serve as Round Table participants. Furthermore, for persons who believe that some affected interest is not adequately represented they may request Round Table membership.

The Agency will convene and chair a Steering Committee in advance of the Round Table meeting. The Steering Committee will address all relevant pre-meeting issues. The Steering Committee will determine the: Round Table Issues; process for preparing issue papers prior to the Round Table; meeting time frames; meeting schedule; and Round Table ground rules. Each party identified above will select one representative to serve on the Steering Committee.

*Final Draft**WJ
LH*

DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

Hazard Analysis and Critical Control Point (HACCP)
Round Table

AGENCY: Food Safety and Inspection Service, USDA

ACTION: Notice

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NATIONAL CATTLEMEN'S ASSOCIATION

1301 Pennsylvania Avenue, N.W. • Suite 300 • Washington, D.C. 20004-1701 • (202) 347-0226 • FAX (202) 638-0607

Headquarters

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December 23, 1993

Ms. Martine M. DiCroce
 SubCommittee on Human Resources & Intergovernmental Relations
 B-350 Rayburn HOB
 Washington, DC 20515

Dear Ms. DiCroce,

Thank you for giving NCA the opportunity to provide edits to the testimony presented during the Committee on Government Operations' hearing - Reinventing the Federal Food Safety System: USDA's Progress in Reforming Meat and Poultry Inspection.

NCA respectfully request that lines 2386 through 2389 and 2441 through 2443, as indicated in the enclosed edits, be stricken from the record. Following my testimony I spoke with Ms. Carol Forman, from the Safe Food Coalition, about NCA's statement. After comparing the respective communications that we each had conducted with different USDA staff, I was compelled to go back to the USDA for further review of the issue.

I have since learned that Ms. Forman did not ask that the HACCP Round Table be delayed. In fact, she asked the same questions I had raised regarding the status of the HACCP proposal and the Department's ability to conduct the Round Table in December as originally outlined.

Given what I have learned, it is no longer accurate nor fair to blame the Safe Food Coalition for delaying the conduct of the HACCP Round Table. Therefore NCA respectfully request that lines 2386 through 2389 and 2441 through 2443 be stricken from our testimony and subsequent Congressional Record.

Sincerely,

Gary Wilson

Director, Animal Health/Inspection and
 Research

APPENDIX 2.—ADDITIONAL MATERIAL FOR THE NOVEMBER 4, 1993, HEARING RECORD

JOHN COMPTON JR. MICHIGAN
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ONE HUNDRED THIRTH CONGRESS

Congress of the United States House of Representatives COMMITTEE ON GOVERNMENT OPERATIONS 2157 RAYBURN HOUSE OFFICE BUILDING WASHINGTON, DC 20515-6143

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INDEPENDENT

MAJORITY—(202) 225-7051
MINORITY—(202) 225-5074

DRAFT

November 1, 1993

MEMORANDUM

TO: Members of the Subcommittee on Human Resources and Intergovernmental Relations

FROM: Edolphus Towns, Chairman

RE: Hearing: "Reinventing the Federal Food Safety System: USDA's Progress in Reforming Meat and Poultry Inspection," Thursday, November 4, 1993, at 9:30 a.m., 2247 RHOB

I. INTRODUCTION

Bad things happen. The Centers for Disease Control and Prevention (CDC) estimates that at least 9,100 people die and another 6.5 million become sick because of food-borne disease annually.¹ However, food-borne illness is largely preventable. Recent outbreaks of food-borne disease as well as the recommendation by Vice President's National Performance Review to consolidate federal food safety responsibilities within the Food and Drug Administration have highlighted the need to "reinvent" the federal food safety system.

II. BACKGROUND

The federal food safety system has evolved piecemeal over the last 100 years, usually in response to specific economic or health threat. Currently, 12 federal agencies spend about \$1 billion annually to administer about 35 laws governing food safety and quality.² However, the General Accounting Office (GAO) has concluded that fundamental differences in agencies' missions, responsibilities, inspection approaches and enforcement authorities have led to fragmented oversight, inconsistent and illogical treatment of food products posing similar risks, inefficient use of resources, and poor interagency coordination.³

The greatest problems lie in the division of responsibility between the two primary agencies--the U.S. Department of Agriculture (USDA), which oversees meat and poultry, and the Food and Drug Administration (FDA), which oversees almost all other food products. Generally, food products under USDA's jurisdiction must be "approved" before marketing whereas food products under FDA's jurisdiction may be marketed without premarket approval subject to post-marketing surveillance and enforcement action. Thus, for example, FSIS carries out a massive "continuous inspection" program at the nation's slaughterhouses, which by law may operate only when one of the department's field inspectors is on duty. FSIS inspects meat animals both before and after slaughter. FSIS also inspects all meat and poultry processing plants daily. In contrast, FDA inspects facilities under its jurisdiction, on average, once every three to five years. The differences in the two organizations' mandates and approaches mean that food products that pose similar risks may receive widely varying scrutiny.

In fiscal year 1993, FSIS devoted over 9,000 staff years and about \$660 million to overseeing about 6,100 slaughter and processing plants--about 400 slaughtering plants, 1,070 combination plants performing both slaughtering and processing operations, and 4,630 processing plants.⁴ FSIS had about 7,800 in-plant inspectors, of whom about 1,100 were veterinarians. In contrast, FDA devoted about 2,700 staff years and almost \$200 million to food safety activities, to overseeing the estimated 53,000 domestic food establishments under its jurisdiction. Due in part to budget constraints, FDA and state inspections cover less than one-fourth of the 53,000 establishments each year.⁵

The incongruities between USDA and FDA extend well beyond their inspection methods. For example, the organizations operate under vastly different enforcement authorities. In contrast to USDA, FDA generally cannot (1) presume that firms are engaged in interstate commerce, (2) require food processors to register, (3) prohibit use of equipment that may contaminate food, and (4) detain domestic products that violate food safety standards.⁶

To overcome the fragmentation of responsibility for food safety, federal agencies have reached more than 50 cooperative agreements. However, jurisdictional disputes and disagreements between agencies have stymied these efforts. For example, USDA and FDA--both of which have authority to regulate egg products--did not develop a unified approach for reducing bacterial contamination in eggs until 1992, 6 years after the public health threat emerged.⁷

Over the last 20 years, may investigators have documented--and criticized--the inconsistencies of the existing arrangement. The Senate Committee on Governmental Affairs reported in 1977 that the division of responsibility between USDA and FDA "has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex.... There is no rationale, other than a historic one, to justify maintaining two separate, inconsistent, and costly systems for inspecting and otherwise regulating production of processed foods."⁸ The subcommittee will be

releasing a report from CRS at the hearing that summarizes previous recommendations for changing the federal organization of food safety responsibilities, including the recent recommendation by the Vice President's National Performance Review to transfer meat and poultry inspection from USDA/FSIS to FDA.

In addition to the fragmented organization, the current federal food safety system is obsolete because it has failed to keep pace with changes in (1) new food-borne threats, (2) the type and source of foods consumed, (3) new food technologies, and (4) consumer behavior and demographics. Many commentators have called for efforts to modernize the food safety system and prepare it for the 21st century.⁹

III. RELEVANT LAWS

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*)
 The Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*)
 Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*)
 Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq.*)

IV. OBJECTIVES OF THE HEARING

This is the first in a series of hearings on the need to revamp the federal food safety system. The first set of hearings will focus on USDA's role. Subsequent hearings will focus FDA's role and options for reinventing food safety.

Specifically, this is the first of a two-part hearing. On November 4, 1993, we will listen to citizens, department critics, industry representatives and others. On a later day in November we will listen to representatives from USDA. During both days we will focus on

- (1) what progress USDA is making in reforming meat and poultry inspection, and
- (2) whether meat and poultry inspection responsibilities should be transferred from USDA to an agency with a more "public health" mission.

V. WITNESSES

The following witnesses will present testimony:

Kiner, Suzanne	Redmond, WA, parent of E. coli 1057:H7 victim
Sowerby, Janis	Saranac, MI, parent of E. coli 0157:H7 victim
Heersink, Mary	Dothan, AL, parent of E. coli 0157:H7 victim and co-founder, Safe Tables Our Priority! (S.T.O.P.!)
Marcuse, Edgar, M.D., M.P.H., F.A.A.P.	

	Director, Ambulatory Care Services, Children's Hospital and Medical Center, Seattle, WA
Blake, Paul, Ph.D.	Chief, Enteric Disease Branch, Division of Bacterial and Mycotic Disease, CDC
Harman, John	Director, Food and Agriculture Issues, RCED/GAO
Ebbitt, James	and Craig Beauchamp, Assistant Inspector Generals for Audit and Investigations, USDA, respectively
Woteki, Catherine, Ph.D.	Director, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences
Foreman, Carol Tucker	President, Foreman & Heidepriem, Inc.
Walker, Bailus, Jr., Ph.D., M.P.H.	Professor and Dean, College of Public Health, University of Oklahoma, and spokesman for the American Public Health Assn.
Crawford, Lester, D.V.M., Ph.D.	Executive Director, American Association of Veterinary Medical Colleges
Menning, Edward, D.V.M., M.P.H.	Executive Vice President, National Association of Federal Veterinarians
Carney, David	Legislative Coordinator, National Joint Council of Food Inspection Locals
Marsden, James, Ph.D.	Vice President for Scientific and Technical Affairs, American Meat Institute
Wilson, Gary	Director, Research Animal Health/Inspection and Food Policy, National Cattlemen's Association

Also invited but not expected to testify:

Colville, Mary	National Broiler Council
Ferreril, Kirk	National Pork Producers' Council
Brandenberger, Joel	National Turkey Federation

VI. MAJOR ISSUES

A. New Food-borne Threats

Of the various sources of food contamination, microbes pose the greatest risk to human health, according to food scientists.¹⁰ Harmful microbes in food cause most cases of acute food-borne illness in the United States each year. Because many cases go undiagnosed and/or unreported, the actual figure is probably much higher than the conservative figure of 6.5 million annually—at least 24 million and perhaps as many as 81

million or more cases, according to an estimate by officials at FDA.¹¹ In fact, **food-borne disease** continues to be a major and **growing public health problem** in the United States that is preventable, according to CDC.¹² Food-borne disease particularly harms infants, children, the elderly and immunocompromised individuals. In addition, the social costs of food-borne illness, such as medical expenses and lost productivity, are estimated to reach between \$4 billion and \$8 billion annually.¹³

The nature of food-borne disease has changed in the last ten years with increasing recognition of emerging pathogens and unusual food sources.¹⁴ Examples of emerging pathogens include *E. coli* 0157:H7, *Campylobacter*, *Listeria monocytogenes*, *Salmonella* enteritidis, and Norwalk virus. Examples of unusual food sources include cantaloupes, tomatoes, and apple cider. Developments in food technology, production and distribution and changes in consumer behavior are changing the nature of food risks. For example, USDA estimates that almost half of the money consumers spend on food now goes to meals and snacks away from home.

Since its identification as a human pathogen in 1982, *E. coli* 0157:H7 has emerged as important cause of food-borne illness in the United States, Canada, and the United Kingdom.¹⁵

1. **E. coli 0157:H7**

Escherichia coli (*E. coli*) is a bacterium that lives in the intestines of humans and animals. Although most strains of this bacterium are harmless, one particular strain, *E. coli* 0157:H7, is known to produce a toxin and can cause bloody diarrhea, hemolytic uremic syndrome (HUS), kidney failure, and death. HUS is a serious disease--more common in children than in adults--that affects the kidneys and blood clotting system.

From November 15, 1992 through February 28, 1993, more than 500 people became ill and 4 people died because of infections with *E. coli* 0157:H7 in 4 western states (Washington, Idaho, California, and Nevada).¹⁶ This widespread outbreak was linked to undercooked hamburgers from Jack-in-the-Box restaurants, a fast-food chain. Although USDA's investigation identified the beef slaughtering and processing plants that supplied the meat from which the hamburgers were made, none of the plants has been singled out as a supplier of the contaminated meat.¹⁷ Although some of the meat was imported from Australia and Canada, USDA's investigation concluded that "The foreign plants are no more or less likely to have been the supplier than the domestic plants investigated."¹⁸

At least nine separate outbreaks of *E. coli* 0157:H7 across the United States have occurred since the western outbreak. According to CDC and other researchers, the incidence of *E. coli* 0157:H7 infection and HUS is increasing.¹⁹ CDC researchers estimate that between 7,670 and 20,450 people become sick and between 150 to 390 people die annually in the U.S. due to *E. coli* 0157:H7.²⁰ USDA's Economic Research

Service estimates that the medical costs and the costs of lost productivity attributed to *E. coli* 0157:H7 range from \$229 million to \$610 million annually.²¹

Ground beef is particular suspect to contamination from *E. coli* 0157:H7 because the process of grinding meat may mix in the pathogen.²² *E. coli* 0157:H7 is killed when meat is thoroughly cooked. Specifically, ground beef should be cooked thoroughly until the interior is no longer pink and the juices are clear. FDA has issued interim recommendations to increase the internal temperature for cooked hamburgers to 155 F. Although most outbreaks of *E. coli* 0157:H7 have been associated with undercooked ground beef or person-to-person transmission, other sources include raw milk, contaminated water, and fresh apple cider. *E. coli* 0157:H7 can survive refrigeration and freezing. Also, very low numbers of it can produce infections.

B. Limitations in Existing Inspection System

The outbreaks of *E. coli* 0157:H7 highlight the limitations in the existing meat and poultry inspection system. For example, the meat that was involved in the western outbreak of *E. coli* 0157:H7 in early 1993 did pass federal inspection. "However, current practices are not designed to eliminate pathogens or guarantee that no pathogens are present on raw meat products."²³ USDA's methods for inspecting meat and poultry cannot detect microbial or chemical contamination. Standard organoleptic inspection procedures—smelling, feeling, and looking at the product—date from an earlier era when easily identifiable conditions, such as obvious disease or spoilage, were considered the chief dangers of these foods. The current system is not designed to detect and control what experts from the National Academy of Sciences (NAS) and others consider to be the greatest risk to public health from meat and poultry at the present time—the potential for microbial contamination. Because *E. coli* 0157:H7 does not cause illness in cattle, animals carrying this bacterium appear normal during inspections and escape detection. In addition, there is no rapid test currently available that can be performed on raw meat and poultry to detect the presence of microbial contamination, according to USDA.

Even if it was capable of detecting *E. coli* 0157:H7, USDA might not automatically condemn the meat. FSIS has argued that current law does not permit the agency to declare raw meat and poultry to be "adulterated" if it contains levels of pathogens that are inherent or naturally occurring in animals, and do not ordinarily render the product injurious to health.²⁴ In addition, FSIS and many other food safety experts believe that it may not be possible to eliminate all microbial pathogens on raw meat and poultry. USDA officials have also testified that costs for testing just 20 percent of all livestock or poultry carcass for the presence of each of the 10 major pathogens could range as high as \$58 billion per year. However, GAO officials and others have questioned FSIS's basis for this estimate.

Since 1985, NAS has issued three reports on the need to move toward a scientific,

risk-based approach to ensure the safety of meat and poultry products.²⁵ In general, the NAS reports recommended that USDA use risk assessment to identify and manage public health risks associated with meat and poultry. They emphasized an approach to inspection called Hazard Analysis and Critical Control Points (HACCP) to prevent safety problems before they occur. The 1985 report identified several characteristics of an optimal meat and poultry inspection program, including

- a trace-back and recall system for animal from final sale to the farm;
- more scientific expertise;
- an inspection system with different levels of intensity, reflecting the degree of public health risk at various stages in the process and other factors;
- development of rapid, inexpensive screening tests to detect chemical and microbial contaminants; and
- enhanced enforcement capabilities and adequate resources.

C. USDA REFORM INITIATIVES

In the wake of the western outbreak of E. coli 0157:H7 Agriculture Secretary Mike Espy and FSIS Administrator Russell Cross announced a new "two track" approach for reforming meat and poultry safety from the farm to the table.²⁶ Track I involves the implementation of six major initiatives for maximizing the performance of the current inspection system. Track II represents the agency's commitment to design, test, and implement the regulatory program of the future. A key component of both tracks is USDA's Pathogen Reduction Program aimed at reducing the likelihood that harmful microorganisms--such as Salmonella, Listeria monocytogenes, or E. coli 0157:H7-- will enter the food supply at key points in the production, distribution, and consumption chain from farm to table.²⁷

1. Track I

The following points make up track I:

- Public ownership: FSIS will seek the views of all its constituencies in an open, participatory decision making process.
- Staff and structure the agency: maximize current program's effectiveness.
- Labor relations: build a strong, mutually supportive relationship

with the employee organizations.

- Pathogen Reduction Program: determine the microbiological status of raw meat and poultry and establish goals for reducing pathogens.
- Consumer service and education: raise consumer awareness levels regarding safety and labeling of meat and poultry products.
- Science and technology: improve the current inspection system using risk analysis, new science, and technological advances.

2. Track II

Track II calls for a longer-term effort to develop an entirely new meat and poultry regulatory program. FSIS planned a three step approach to implement Track II:

- Step 1: Conduct regional public hearings,
- Step 2: Conduct a worldwide assessment of emerging technologies, and
- Step 3: Hold meat and poultry conference to determine future meat and poultry regulatory program.

3. Pathogen Reduction Program

USDA's Pathogen Reduction Program is based on HACCP principles to identify critical control points throughout the production/processing cycle, including (1) the live animal, (2) the slaughter process, (3) the processing plant, (4) the food service process, and (5) consumer education.

a. Live animal activities

- Conduct comprehensive research to determine the source and incidence of E. coli 0157:H7 and other pathogens.
- Conduct on-farm investigations to confirm current assumptions about sources of contaminants.
- Develop rapid methods for identifying pathogens.
- Establish methods for the identification and traceback of animals.

- Develop on-farm pathogen prevention program.
- b. Slaughter plant activities**
 - Expand microbiological baseline program to add cows to national microbiological baseline monitoring (initially limited to steers and heifers); expand baseline monitoring to poultry and swine.
 - Evaluate current slaughter and processing methods.
 - Use organic acid and other preventive substances to reduce pathogens on surfaces of beef carcasses.
 - Test "disabled" and other "suspect" animals to determine if *E. coli* 0157:H7 is more prevalent in "sick" animals.
 - Enhance veterinary coverage of higher risk slaughter plants.
 - Mandate improved recordkeeping for slaughter plants.
- c. Processing plant activities**
 - Establish and enforce strict time and temperature requirements to control bacteria in meat trimmings.
 - Finalize "patties" regulation for cooking and handling of patties produced at establishments.
 - Mandate safe-handling labels for all raw meat and poultry products.
 - Research irradiation to support a petition for FDA approval of irradiation for fresh ground beef and beef trimmings.
 - Evaluate inspection in processing plants.
 - Ensure complete and accurate recordkeeping for all transactions.
- d. Food service step activities**
 - Sponsor teleconference to share information on food safety requirements.

- Help state enforcement programs.
- Educate food handlers, including fast-food restaurant employees, about proper cooking and handling.
- Label school lunch products.
- Enhance model codes by working with FDA and the states to ensure adequate controls in the model retail code.
- e. Consumer awareness step activities
 - Enhance consumer awareness campaign.
 - Promote consumer education materials.
 - Promote the USDA's toll free meat and poultry hotline.
 - Expand food safety education.

4. Planned Time Frame for Implementation

On February 5, 1993, Secretary Espy testified that 14 of the 33 initiatives that the Department presented could be implemented in less than 12 months. Although some of the Department's initiatives have no ending time because they are research efforts, Dr. Hollingsworth, Assistant to the Administrator, FSIS, also testified that 14 of 33 initiatives could be accomplished within 12 months or less, some of them as quickly as 2 months.²⁸

D. STATUS OF USDA'S REFORM INITIATIVES

The status of USDA's reform initiatives is unclear and controversial and a major reason for convening this hearing. We plan to listen to critiques of the extent of USDA's progress in implementing its reform initiatives at the November 4, 1993 hearing. Subcommittee staff will prepare a more detailed memorandum on each initiative prior to the second day hearing with USDA to be scheduled later in November 1993.

On October 4, 1993, we asked Secretary Espy to provide a status report on USDA's initiatives. Specifically, we asked him to provide a brief description, the estimated level of effort needed to achieve the objective (e.g., staff years and resources), the projected timetable to completion, and results to date. The Department has not yet complied with this request. Instead, FSIS staff have provided a package of reports, newsletters, and background documents for several of the major initiatives. During a meeting with USDA officials on October 15, 1993, including the Deputy Assistant

Secretary for Marketing and Inspection, Pat Jensen, FSIS officials claimed that there is no overall management plan for the initiatives.

Although USDA has completed several of its specific initiatives--such as conducting six field hearings this summer to obtain public input on its current program and reform efforts--critics have challenged USDA's commitment to change because several initiatives have been delayed or disrupted. In brief, critics claim that not much has changed in the 11 months since the western outbreak of *E. coli* 0157:H7.

A few examples demonstrate the uncertain status of several of USDA's reform initiatives:

- On May 27, 1993, Secretary Espy announced that regulations would be proposed within 90 days requiring plants to adopt HACCP procedures. In September, Department officials announced that USDA had postponed mandating HACCP so that it could conduct further public hearings on the components of such a system.
- On August 16, 1993, USDA published an interim rule in the Federal Register to require safe handling instructions on all meat and poultry product labels by October 15, 1993. On October 14, 1993, a U.S. District Court Judge in Austin, TX, blocked the rule on the grounds that USDA violated the Administrative Procedures Act by not following the notice-and-comment procedure. The judge disagreed with USDA's assertion that several recent outbreaks of *E. coli* 0157:H7 represented a public health emergency that justified issuance of an interim rule. In addition, the judge took issue with the manner in which USDA developed the interim rule.²⁹
- On May 27, 1993, Secretary Espy announced that, within 30 days of the end of the public hearings, USDA would present a package of legislative proposals to strengthen USDA's authority. The hearings ended June 18, 1993, but the Department has not yet put forward its legislative proposals.

E. VICE PRESIDENT'S RECOMMENDATION

Consumer groups, industry representatives, labor unions, and others have grown increasingly frustrated by the pace of USDA's reform initiatives. For example, consumer critics point out that over 8 years since the first NAS report, USDA still has not conducted a basic assessment of health risks associated with consumption of meat and poultry products, has not yet developed and implemented rapid diagnostic tests to detect pathogens, has not sufficiently broadened the base of scientific expertise of its staff, and has not yet developed a trace-back and recall system.³⁰ Critics believe that USDA has made little progress because it must play two roles--promoting agriculture and protecting the public.

On September 7, 1993, the Vice President's National Performance Review recommended, "Eliminate the Food Safety and Inspection Service as a separate agency by consolidating all food safety responsibilities under the Food and Drug Administration."³¹ The report cited problems with duplication and gaps in coverage and argued that streamlining and enhancing enforcement authority would allow FDA to develop a scientifically based system for inspections. The details of the proposal are expected to be released in a report on the Department of Health and Human Resources sometime this fall.

The Vice President's proposal has been controversial. Consumer groups generally support the proposal of transferring food safety responsibilities from USDA to FDA or an agency with an explicit "public health" mission. Industry groups and USDA's inspectors' union believe that (1) reorganization should only be considered after USDA has had an opportunity to implement its reform initiatives and (2) that the Vice President's proposal fails to consider the need to maintain a "farm-to-table" approach to food safety. Transferring only FSIS to FDA would sacrifice progress within USDA's Animal and Plant Health Inspection Service and extension service. If food safety is consolidated, these groups believe it should be consolidated within USDA.

Although the Vice President's proposal is one of several that have been suggested to reorganize federal food safety efforts, most of the proposals have dealt with the organizational scheme and not the objective or mission of federal food safety efforts. What may be missing is the need to develop a comprehensive federal food safety policy.

VII. CONCLUSION

To adequately consider the basis of the Vice President's recommendation it is necessary to review the performance of federal organizations that are currently responsible for ensuring the safety of the nation's food supply. The larger question to consider during these hearings is whether the American taxpayers are getting their money's worth from the existing federal food safety system. Historically, advances in the U.S. public health system have occurred as a result of one or more major health crises. How may more children will die from E. coli 0157:H7 before the system is improved?

VIII. ENDNOTES

1. John V. Bennett *et al.*, "Infectious and Parasitic Diseases," in Closing the Gap: The Burden of Unnecessary Illness, eds. Robert W. Amler and H. Bruce Dull (New York: Oxford University Press, 1987), pp. 102-114.

2. Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A and 19B, Dec. 21, 1990).

3. Food and Agriculture Issues: Revamping the Federal Food Safety System (GAO/OCG-93-15TR, Dec. 1992). See also, Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

4. See Geoffrey S. Becker, "Meat and Poultry Inspection: Background and Current Issues," (CRS-93-574 ENR, June 9, 1993). FSIS's budget includes nearly \$500 million from congressional appropriations and the balance from industry fees charged for inspector overtime. There are also about 300 Talmadge-Aiken plants that are plants that prepare meat and poultry for interstate commerce, operate under federal procedures with federal funds, but are staffed by federally-trained state employees.

5. Comprehensive Needs Assessment: 1994-1997 (FDA, Department of Health and Human Services, 1990), p. B18.

6. See GAO's Uniform, Risk-based Inspection report at p. 28.

7. Food Safety and Quality: Salmonella Control Efforts Show Need for More Coordination (GAO/RCED-92-69, April 21, 1992).

8. United States Senate, Committee on Governmental Affairs, Study on Federal Regulation: Vol. V, Regulatory Organization, No. 95-91, Dec. 1977, p. 139.

9. For example, see, Memorandum from David Kessler, Commissioner, FDA, to the Secretary, HHS, "Food Safety Initiative--Action," March 12, 1993, in subcommittee's files.

10. Presentation by Dr. Stanford Miller, University of Texas Health Science Center, before a workshop sponsored by The Food Forum, "Prioritizing, Managing and Communicating Food Safety Risks: Dealing With What Bugs Us," Food & Nutrition Board, Institute of Medicine, National Academy of Sciences, Washington, DC, Sept. 14, 1993.

11. Douglas L. Archer and John E. Kvenberg, "Incidence and Cost of Foodborne Diarrheal Disease in the United States," Journal of Food Protection 48 (1985), pp. 887-894.

12. Written testimony of Dr. Paul Blake, Chief of the Enteric Diseases Br., Division of Bacterial and Mycotic Diseases, CDC, Feb. 5, 1993, Hearing, Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation, Senate Committee on Agriculture, p. 48. See also testimony of Dr. James Hughes, Director, National Center for Infectious Diseases, CDC, March 16, 1993, Joint Hearing, Subcommittee on Department Operations and Nutrition and Subcommittee on Livestock, House Committee on Agriculture, p. 87.

13. Tanya Roberts and David Smallwood, "Data Needs to Address Economic Issues in Food Safety," American Journal of Agricultural Economics, Aug. 1991, p. 935.

14. Kristine L. MacDonald and Michael T. Osterholm, "The Emergence of *Escherichia coli* 0157:H7 Infection in the United States," JAMA (May 5, 1993, vol. 269, no. 17), p. 2265. See also, Emerging Infections: Microbial Threats to Health in the United States (Washington, D.C.: National Academy Press, 1992).

15. Lee W. Riley, et al, "Hemorrhagic Colitis Associated With a Rare *Escherichia Coli* Serotype," N. Engl. J. Med. 1983; 308:681-5.

16. Morbidity and Mortality Weekly Report (MMWR), Centers for Disease Control and Prevention, Vol. 42, No. 14, April 16, 1993, p. 258.

17. "Report on the *Escherichia coli* 0157:H7 Outbreak in the Western States," USDA/FSIS, May 21, 1993, p. 1.

18. Ibid, p. 13.

19. Patricia M. Griffin and Robert V. Tauxe, "*Escherichia coli* 0157:H7 Human Illness in North America, Food Vehicles and Animal Reservoirs," International Food Safety News, vol. 2, no. 2, 1993, p. 15. See also Edward A. Belongia, et al, "An Outbreak of *Escherichia coli* 0157:H7 Colitis Associated with Consumption of Precooked Meat Patties," The Journal of Infectious Diseases, 1991; 164:338-43.

20. Agricultural Outlook, Economic Research Service, USDA (June 1993), p. 32.

21. Ibid.

22. MMWR, April 16, 1993, p. 262.

23. U.S. Department of Agriculture, "Report on the *Escherichia coli* 0157:H7 Outbreak in the Western States," May 21, 1993, p. 1.

24. See Meat and Poultry Inspection: Background and Current Issues (CRS, 93-574 ENR, June 9, 1993). Lawyers for consumer advocates have disputed FSIS's interpretation of the law.

25. See Meat and Poultry Inspection: The Scientific Basis of the Nation's Program (Washington, D.C.: National Academy Press, 1985); Poultry Inspection: The Basis for a Risk-Assessment Approach (Washington, D.C.: National Academy Press, 1987); Cattle Inspection (Washington, D.C.: National Academy Press, 1990).

26. Written testimony of Dr. H. Russell Cross, Administrator, FSIS, USDA, Feb. 5, 1993, Hearing, Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation, Senate Committee on Agriculture, pp. 18-24.

27. This section relies heavily on Pathogen Reduction Program: The War on Pathogens, FSIS/USDA, undated; Evolution to Revolution: New Directions for Meat and Poultry Regulation--Proposed FSIS Strategic Plan, FSIS/USDA, August 1993; the Feb. and March 1993 hearings; and CRS's Current Issues Report on Meat and Poultry Inspection, June 9, 1993.

28. U.S. Senate, "Food Safety and Government Regulation of Coliform Bacteria," Hearing before the Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation, Committee on Agriculture, Feb. 5, 1993, p. 26.

29. "It is disingenuous for the USDA to express the urgent need for an emergency rule and then delay its effective date for 60 days, when the USDA could have followed the standard procedure for rulemaking under the APA within such a time period. If there truly was an epidemic problem or anywhere close to such a problem, the USDA presumably would have required a much shorter period for the effective date of the emergency rule." Texas Food Industry et. al. v. USDA No. 93-CA-586 (W.D. TEX. Oct. 14, 1993).

30. CRS, June 9, 1993, Summary.

31. Vice President Al Gore, "From Red Tape to Results: Creating a Government That Works Better & Costs Less," Report of the National Performance Review. (Washington, D.C.: Sept. 7, 1993), p. 101.

FROM RED TAPE TO RESULTS

CREATING A GOVERNMENT THAT WORKS BETTER & COSTS LESS

Report of
the National
Performance Review

Vice President Al Gore

September 7, 1993

Action: Eliminate the Food Safety and Inspection Service as a separate agency by consolidating all food safety responsibilities under the Food and Drug Administration.²⁶

Sometimes duplication among federal programs can make us ill—even kill us. Take the way we inspect food for contamination. Several agencies are involved, each operating under separate legislation, with different standards, and with staff trained in different procedures. In 1992, the Food and Drug Administration (FDA)—part of the Department of Health and Human Services—devoted about 255 staff years to inspecting 53,000 food stores, while the Food Safety and Inspection Service (FSIS)—part of the Department of Agriculture—devoted 9,000 staff years to inspecting 6,100 food processing plants.

But this duplication doesn't mean that we cover all sources of contamination thoroughly. Meat and poultry products must be inspected daily, while shellfish, which have the same risk of causing food borne illness, are not required by law to be federally inspected. Too many items fall through the bureaucratic cracks. Not only that, enforcement powers vary among the different agencies. If the FDA finds unsanitary plant conditions or contaminated products, compliance is usually voluntary because the agency lacks FSIS's powers to close plants or seize or detain suspect or known contaminated products. And if one agency refers a problem to another, follow up is at best slow and at worst ignored.²⁷

With no fewer than 21 agencies engaged in research on food safety, often duplicating each other's efforts, we aren't progressing fast enough in understanding and overcoming life-threatening illness. As recent and fatal outbreaks of food-borne illness attest, multiple agencies aren't adequately protecting Americans.

Under our recommended streamlining, the FDA would handle all food safety regulations and inspection, spanning the work of the many different agencies now

involved. The new FDA would have the power to require all food processing plants to identify the danger points in their processes on which safety inspections would focus. Where and how inspections are carried out, not the number or frequency of inspections, determines the efficiency of the system.

The FDA would also develop rigorous, scientifically based systems for conducting inspections. Today, we rely, primarily, on inspection by touch, sight, and smell. Modern technology allows more reliable methods. We should employ the full power of modern technology to detect the presence of microbes, giving Americans the best possible protection. Wherever possible, reporting should be automated so that high-risk foods and high-risk food processors can be found quickly. Enforcement powers should be uniform for all types of foods, with incentives built in to reward businesses with strong safety records.

Action: Consolidate non-military international broadcasting.²⁸

The U.S. government funds several overseas broadcasting services—including those operated by the United States Information Agency's Bureau of Broadcasting, which accounts for one-third of the agency's \$1.2 billion budget, and services such as Radio Free Europe and Radio Liberty, which have budgets totalling \$220 million a year. All non-military international broadcasting services should be consolidated under the USIA. Part of this was proposed in the President's budget request for fiscal year 1994.

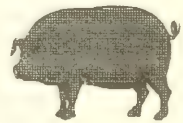
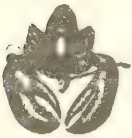
Action: Create a single civilian polar satellite system.²⁹

Collecting temperature, moisture, and other weather and environmental information from polar satellites is a vital task, both for weather forecasting and for global climate studies. But we have two different systems, one run by the Department of Defense and the other by

5. National Performance Review Accompanying Report, *Transforming Organizational Structures* (Washington, D.C.: U.S. GPO, September 1993).
6. National Performance Review Accompanying Report, *Department of Agriculture* (Washington, D.C.: U.S. GPO, September 1993).
7. U.S. General Accounting Office (GAO), *U.S. Department of Agriculture: Farm Agencies' Field Structure Needs Major Overhaul*, RCED-91-09 (Washington, D.C.: January 1991), p. 10.
8. National Performance Review Accompanying Report, *Housing and Urban Development* (Washington, D.C.: U.S. GPO, September 1993).
9. Ibid.
10. National Performance Review Accompanying Report, *Department of Energy* (Washington, D.C.: September 1993).
11. National Performance Review Accompanying Report, *Department of Defense* (Washington, D.C.: U.S. GPO, September 1993).
12. National Performance Review Accompanying Report, *Small Business Administration* (Washington, D.C.: U.S. GPO, September 1993).
13. National Performance Review Accompanying Report, *U.S. Agency for International Development*, (Washington, D.C.: U.S. GPO, September 1993).
14. National Performance Review Accompanying Report, *Department of State* (Washington, D.C.: U.S. GPO, September 1993).
15. Ibid.
16. Ibid.
17. National Performance Review Accompanying Report, *Department of Energy* (Washington, D.C.: U.S. GPO, September 1993).
18. National Performance Review Accompanying Report, *Department of Transportation* (Washington, D.C.: U.S. GPO, September 1993).
19. *Department of Defense*.
20. National Performance Review, Accompanying Report, *Reinventing Federal Procurement* (Washington, D.C.: U.S. GPO, September 1993).
21. National Performance Review Accompanying Report, *Intelligence Community* (Washington, D.C.: U.S. GPO, September 1993).
22. National Performance Review Accompanying Report, *Department of Labor* (Washington, D.C.: U.S. GPO, September 1993).
23. GAO, *Dislocated Workers: Comparison of Assistance Programs*, Briefing Report to Congressional Requesters, GAO/HRD-92-153BR (Washington D.C., September 1992), p. 2.
24. *Department of Agriculture and Department of Labor*.
25. National Performance Review Accompanying Report, *Department of Education* (Washington, D.C.: U.S. GPO, September 1993).
26. National Performance Review Accompanying Report, *Health and Human Services* (Washington, D.C.: U.S. GPO, September 1993).
27. Ibid.
28. *Department of State*.
29. National Performance Review Accompanying Report, *Department of Commerce* (Washington, D.C.: U.S. GPO, September 1993).
30. *Health and Human Services*.
31. Ibid.
32. National Performance Review Accompanying Report, *Department of Justice* (Washington, D.C.: U.S. GPO, September 1993).
33. *Department of Agriculture*.
34. U.S. Department of Agriculture, Office of the Inspector General, International Affairs, Commodity Programs, and Science and Education Division, *Report on Agricultural Stabilization and Conservation Service* (Washington D.C.: Department of Agriculture, May 1993), p. 11.
35. *Department of Transportation*.
36. U.S. General Accounting Office, Highway Demonstration Projects: Improved Selection and Funding Controls Are Needed (Washington, DC: GAO, 1991), pp. 1-6.
37. *Department of Transportation*.
38. National Performance Review Accompanying Report, *Department of the Interior* (Washington, D.C.: U.S. GPO, September 1993).
39. Ibid.
40. *Health and Human Services*.
41. National Performance Review Accompanying Report, *Department of Veterans Affairs* (Washington, D.C.: U.S. GPO, September 1993).
42. *Department of Defense*.
43. *Department of Energy*.
44. Office of Management and Budget (OMB), *Fact Sheet on Reform of Federal Power Marketing Administration Debt Repayment Practices* (Washington D.C., 1990), p. 3.
45. OMB, *Status Report on Credit Management and Debt Collection*, Report to Congress (Washington D.C., 1993), p. 1.
46. National Performance Review Accompanying Report, *Improving Financial Management* (Washington, D.C.: U.S. GPO, September 1993).
47. *Department of Justice*.
48. *Department of the Interior*.



Develop A National, Uniform, Scientific, Risk-Based Inspection System To Ensure A Safe Food Supply



National Performance Review Food Safety Working Group



NATIONAL PERFORMANCE REVIEW

FOOD SAFETY WORKING GROUP

The National Performance Review convened a working group on food safety to define the parameters of a uniform, scientific, risk-based inspection system. The following members met June 28 and 29, 1993 to discuss these issues, and have spent the past months refining the enclosed document:

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Karen Henderson, member of the National Performance Review, served as moderator for the two day session. GAO Report RCED-92-152, June, 1992, Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply, and other materials made available to the Working Group provided valuable background on the problems with the current National

food safety inspection system. Recommendations were developed to address these problems, and to also address other food safety issues identified by the group. The consensus of the working group was that a new, independent food safety agency is needed to correct problems in the present system. Other options were addressed but were not as effective in assuring protection of the nation's food supply. A detailed description of the functions and characteristics of this new agency are addressed in our report recommendations.

EXECUTIVE SUMMARY

Today, this country's food safety and inspection system is a complex regulatory network consisting of 35 laws and involving 12 different agencies. The system is cumbersome, inefficient and ineffective. It can not adequately protect the consumer against all sources of foodborne illness and economic fraud.

Naturally occurring toxins, such as domoic acid and ciguatoxin in seafood, mold toxins in grains, beans and nuts, and bacterial toxins, such as staphylococcus enterotoxin cause serious illnesses in consumers.

Microorganisms, such as *Vibrio vulnificus*, *Listeria*, *Salmonella*, *Campylobacter*, *E. Coli* 0157:H7 in seafood, meat, and poultry, are responsible for outbreaks of foodborne infections that may result in death, disabling diseases, and significant economic losses for the country. Parasites, such as trichina, toxoplasma and the anisakidae in food animals and seafood are continuing foodborne hazards.

Residues from the use of animal drugs and industrial and agricultural chemicals in foods can cause acute illness and may be the source of long term health problems when consumed on a chronic basis. These, and many other foodborne disease agents, are justifiably of great concern to this country's consumers.

Widespread outbreaks of acute foodborne disease occur unexpectedly with severe health and economic consequences. The suffering and economic losses from chronic disease, while difficult to measure is believed to be significant. Economic fraud becomes more sophisticated, more profitable for perpetrators, and more difficult for consumers to detect each year.

A food inspection system is needed that protects the consumers by adequately addressing the above problems. This system must use inspection

methods proven to be effective, and new and innovative strategies and techniques. At the present time, the frequency and intensity of inspection is driven as much by law as by science. Certain food processing facilities, preparing foods that pose similar health risks, may be inspected daily by the Food Safety and Inspection Service, U.S. Department of Agriculture, but may be inspected only once every three to five years by the Food and Drug Administration, U.S. Department of Health and Human Services. The current food inspection programs have overlapping and duplicate inspections, and inspection efforts are sometimes poorly coordinated. Insanitary and other unacceptable conditions can persist in an establishment because the inspector present in the plant does not have authority to take action against a product or process for which another agency has legal oversight. The statutory enforcement authority of some food inspection agencies is significantly lacking, and what tools exist are inefficient to do the job.

Food safety research is conducted by 21 agencies with little or no coordination and much duplication of effort. This causes research money to be used on similar projects in different agencies. Research funds are often wasted that should be used for the evaluation of emerging food related health problems, and the development of new technology for controlling current and emerging problems.

The creation of a single, independent, food safety agency that is responsible for administering a uniform set of scientifically-based food safety laws would provide a regulatory system that is cost efficient and capable of assuring a wholesome, honestly labeled, and unadulterated food supply for this nation's consumers. It would eliminate the overlapping and duplicative efforts now existing in this country's food safety programs; eliminate illogical and

inconsistent treatment of food products posing similar risks; avoid problems associated with ineffective interagency agreements; consolidate federal food safety appropriations; and reduce administrative costs by eliminating redundant overhead.

This agency must have a public health based, consumer service mission. It must concentrate on the prevention and control of foodborne illness and food related fraud, and on continuous improvement of its operations. It must be scientific, basing inspections on professional medical knowledge of the risks associated with the foodborne health hazards and the compliance histories of the food processing establishments. There must be an effective food safety research component staffed by qualified research scientists, and there must be statutory enforcement authority that is fully adequate for the protection of the nation's food supply. It is imperative that the agency be managed by qualified medical and scientific professionals experienced in the control of food related public health problems, and there must be adequate epidemiological and public health data provided on foodborne illnesses to adequately measure the effectiveness of this agency in protecting the consumer.

The working group is confident that any agency meeting the above criteria should be answerable to the consumers for whom these vital services are provided, and therefore must be unincumbered by competing priorities of departments within which such food safety agencies currently reside. An independent food safety agency would assure a separate budget process and direct communication with Congress on food safety issues. This working group recommends that the new food safety agency be independent, not within the departments that currently exist, and principally answerable to the consumers for whom this vital service is provided.

DEVELOP A NATIONAL, UNIFORM, SCIENTIFIC, RISK-BASED INSPECTION SYSTEM TO ENSURE A SAFE FOOD SUPPLY

Background

The Centers for Disease Control and Prevention, (CDC), U S Department of Health and Human Services, (HHS) estimates that at least 9,000 Americans die from foodborne illness each year, and that 6.5 million become sick from eating contaminated foods. Because many of these cases go undiagnosed, the actual figure is probably much higher than the conservative estimate of 6.5 million. The estimate by officials at the Food and Drug Administration (FDA) is, in fact, much higher - at least 24 million. The current system of determining the prevalence of foodborne illness in this country is inadequate in many respects. An effective system, such as that which is currently utilized in the State of Minnesota, is needed to provide accurate national data. Resources are not always available to investigate foodborne illness so that outbreaks can be recognized. An effective system is needed to provide accurate national data. This is an essential element that is currently missing from the tools available for planning and evaluating the effectiveness of our food safety inspection system.

Most of the cases of foodborne illness today can be traced to meat, poultry, eggs, milk, fish and shellfish. Shellfish alone caused 21 percent of all reported food poisonings arising from the consumption of meat, fish, or poultry between 1978 and 1987. Toxins, natural in origin, such as domoic acid, ciguatera toxin and aflatoxin are regularly found in seafoods, grains, nuts and dried beans. Food can be contaminated with harmful microorganisms, such as bacteria, viruses, and fungi, parasites, such as tapeworms, roundworms and flukes, chemicals, such as pesticides, animal drugs, flavor and color additives, and agricultural or industrial chemicals. All such foodborne health hazards can, and do, regularly cause human illness. In recent years, a number of outbreaks of foodborne illness caused by highly pathogenic bacteria have called attention to the particular importance of these organisms. Typical foods involved have included cheese contaminated with *Listeria*, milk and cantaloupe contaminated with *Salmonella*, canned mushrooms contaminated with *Staphylococcus*, and

hamburger contaminated with *E. coli* 0157 H7. However, the great variety of foodborne hazards that exist and their acute or chronic impact on the health of consumers, as in the case of the contamination of foods with chemicals which may contribute to increased numbers of cases of cancer and birth defects, are no less important.

Some of the current factors contributing to foodborne illness seem to be an outgrowth of major changes in food production, processing, distribution and preparation systems, and the increased vulnerability of certain segments of the population. Today high speed, mass production food processing systems move vast quantities of meat, poultry and seafoods, and processed foods to all parts of the country within hours after production. Large volumes of food are imported from countries whose food production and processing industries are not under U.S. control. As a consequence, when outbreaks of foodborne illness occur, the outbreak may be widespread and the numbers of persons affected may be very large.

Today, more meals are eaten outside the home, and more of the foods eaten in the home are pre-prepared in some respect. As a result, consumers have less control over the safety of their food and its preparation. The utilization of unwholesome raw materials or poor hygienic controls during commercial processing and preparation for consumption can have dire consequences. While the U.S. population is generally healthy, certain important segments of our society are more susceptible to foodborne disease than the general population. These include the very old, the very young and the increasing numbers of persons who are immunologically suppressed, by a disease process or the therapeutic agents used to control the effects of a disease. This is a population that must be considered when establishing public policy related to how safe a food supply should be. Some foodborne bacteria, including *Salmonella*, have been associated with chronic diseases such as arthritis. The parasite *Toxoplasma gondii* has been shown to cause dementia in immunocompromised individuals, including more than 50 percent of AIDS patients. The incidence of *Mycobacterium avium* in immunocompromised persons is also rapidly on the rise.

The prevention and control of foodborne illness and foodborne disease outbreaks is of great economic importance. These illnesses and outbreaks are expensive not only for those who are ill, but also for society. An April 1985 *Journal of Food Protection* article estimated that foodborne illnesses in the U.S. costs between \$1 to \$10 billion annually. This figure

includes direct medical costs, lost wages and productivity, and industry loss through embargo, voluntary destruction and recall. The article stated that "Any money spent on research, surveillance and public education would be only a small fraction of the cost otherwise borne by the economy when disease occurs. In most instances food supplier losses in the form of recalls, lost business, legal fees, legal settlements and wages exceeded the medical costs and lost earnings of the victims, thus the indirect cost to the economy may equal or even double the patient-related cost estimates."

A July 1988 *Journal of Food Protection* article indicated that a preliminary estimate, based on an estimate of 12.6 million cases of foodborne illness per year, is \$8.4 billion annually. The article stated that "Microbiological disease, bacterial and viral, represent 84 percent of the United States' costs with salmonellosis \$4 billion, staphylococcal \$1.5 billion, toxoplasmosis \$445 million, listeriosis \$313 million, campylobacteriosis \$156 million, trichinosis \$144 million, *Clostridium perfringens* enteritis \$123 million; *E. coli* \$123 million; botulism: \$322,200 per case..."

In June, 1993, *Agriculture Outlook* reported "USDA's Economic Research Service (ERS) has estimated that medical costs and productivity losses from foodborne disease caused by several major bacterial pathogens--*Salmonella*, *Campylobacter jejuni* or *coli*, *E. coli* O157 H7, and *Listeria monocytogenes* are between \$2.5 and \$3.4 billion annually. Costs for several major parasitic foodborne diseases--*Toxoplasma gondii*, *Trichinella spiralis*, *Taenia saginata*, and *Taenia solium* were estimated at \$2.6 billion annually." These annual estimates for 1992 excluded toxoplasmic encephalitis infections in 2,250 - 10,200 AIDS patients, 50 percent of which may have a foodborne origin."

The *New England Journal of Medicine*, August, 1978 published a study conducted by CDC on the impact of one foodborne disease--salmonellosis. The study showed that "salmonellosis is much more than an inconvenience --it is responsible for complications, operations and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly." The study also demonstrated that "salmonellosis is expensive not only for those who are ill, but also for society because such outbreaks adversely affect the economy." The study stated "Since salmonellosis is a preventable disease, the cost of public-health programs to detect, control, and prevent salmonellosis must

be measured against the unnecessary medical expenses and loss-of-productivity costs, which may be more than a billion dollars a year " It is clear that as this administration works diligently to improve the economy, reduce the deficit, and reform health care, the prevention and control of foodborne disease outbreaks must be thoroughly addressed

Enormous profits can be made by persons, or organizations, that adulterate foods or deal in foods that are unwholesome The methods available for adding cheap or worthless components to foods, or for concealing unwholesomeness and inferiority, particularly of the expensive foods of animal origin, are numerous, highly sophisticated and easily applied Control of food associated fraud is important to the dietary health, the value of the food dollar and the confidence of the consumer in the safety and quality of the nations food supply Unwholesome, adulterated foods compete unfairly in the marketplace with foods that are wholesome and free of adulteration An effective regulatory system is needed to act on behalf of consumers, and the food industry, to prevent such practices, when possible, and to take the profit out of such practices when they are found to occur.

There are inconsistent and illogical differences between the different agencies' approaches and enforcement authorities which weaken the systems effectiveness. It is not uncommon for the actions taken to enforce the regulatory standards for safety, in a food processing plant, to be determined by the legislation that governs the responsible agency, and not by an assessment of the actual risk that product poses to public health or economic fraud Also, differing regulatory approaches, jurisdictional conflicts among agencies, and the inability to reallocate resources across agencies have resulted in a system that fails to fully protect the public's health and prevent economic fraud.

1) The present food protection programs do not adequately meet the current regulatory needs of the country.

Viewed in its entirety, the existing food protection structure is inefficient, cumbersome and costly An optimal system of control would be one with different levels of intensity of inspection, reflecting the degree of public health risk and fraud associated with the particular food or food product It would have an effective monitoring system, and an accurate compliance history of each establishment in the food industry Its objectives should be that of

serving the nation's consumers, and it should be free to establish public policy, related to the protection of food, independent of the undue pressures and influence of the regulated industry and its political advocates. The current food inspection network of programs does not meet this criteria.

2) The present food protection system is not adequate to fully protect the consumer against foodborne illness.

A system is needed that applies the sciences associated with food hygiene and control of food related fraud based on priorities established by the careful evaluation of the risks associated with the products and their producers.

The food industry must be encouraged, and if necessary, assisted in the voluntary application of process control systems which allow processors to focus more effectively on public health related hazards in their food production processes. One example of such a control process is the Hazard Analysis Critical Control Point (HACCP) system.

HACCP is a system of sanitation and process control for the manufacturing and processing of food products. It is capable, when correctly applied, of assuring food safety and wholesomeness and preventing economic adulteration.

The system requires that a manufacturer develop a specific HACCP plan for each category of products produced. The development of such programs could be assisted by agency experts and become an important consideration in the evaluation of the quality of a particular manufacturer's capability for producing wholesome unadulterated foods. Systems, such as HACCP, could be a major factor in improving the food industry's motivation and ability to carry out its legal responsibility for identifying and controlling public health hazards and food-associated economic fraud.

A National Academy of Sciences committee has indicated that an optimal inspection system is one with different levels of intensity based on the degree of public health risk at various stages in the production process, and has a reliable monitoring system, and an accurate compliance history of each processing plant, while addressing the food protection needs of the consumer. Process control procedures, such as HACCP, concentrate on the critical control points in the processes that potentially pose public health risk. A food

protection agency must have a reliable monitoring system and an accurate compliance history of food establishments. Without such information the inspection system would lack the vital components of an effective consumer protection program

3) The current food protection programs are inconsistent in the intensity and frequency of inspection for foods posing similar risks.

FDA inspectors responsible for inspecting much of the nations food supply are also responsible for inspecting firms that produce medical devices, drug manufacturing facilities, and blood banks. A limited budget and limited numbers of inspectors have resulted in agency policies that often assign these medical support firms higher control priority than food processing plants producing "high-risk" foods, such as low acid canned foods and infant formulas. Medical device producers are always assigned a higher inspection priority than "low-risk" food facilities, such as bakeries, warehouses, and bottling plants. Although FDA attempts to assign a risk priority to foods by assigning them to these "high" or "low" risk categories, the assignment of inspection frequency is, in practice, inconsistent and not based on a true evaluation of the health and fraud risks presented by such foods. The frequency of inspection is most often based on the availability of resources. Availability is often controlled by the presence of a crisis in the drug or medical supply industry, or with the nations blood supply. Such a crisis usually demands that FDA concentrate its limited resources on the crisis issue, thus further reducing the already infrequent inspection of food manufacturing firms. A recent GAO report indicated that on the average, FDA inspects food establishments once every three to five years.

The Federal Meat Inspection Act of 1907 and the Poultry Products Inspection Act of 1957 (both Acts were updated in the late 1960s) mandate that the Department of Agriculture provide continuous inspections at slaughter plants examining each carcass. Such inspections are a critical point in the elimination of diseased and otherwise unwholesome meat and poultry from the food supply. For example, in 1989 these inspectors eliminated an enormous number of diseased food animals from our nation's meat supply - approximately 70,000,000 head of poultry, 140,000 cattle and 181,000 pigs. This is of particular importance to the task of protecting consumers from foodborne disease because many of the disease agents that are

particularly hazardous to humans may be carried by and transmitted through the meat of diseased food animals. The requirement, and justification, for this kind of inspection is unique to food animals.

The Acts also mandate that inspectors visit meat and poultry processing plants on a minimum daily basis. The law is inflexible in allowing FSIS to reduce the minimum number of inspections. GAO Report RCED-92-152 states "in fiscal year 1991, FSIS devoted about 9000 staff years to oversee about 6,100 establishments, while FDA devoted about 255 staff years to oversee an estimated 53,000 food establishments." This statement referred to the inspection of domestic food establishments, and did not include import inspections. The two agencies also have different approaches for some foods that appear to pose similar risks. For example, beef broth is inspected daily by FSIS, while plants manufacturing chicken broth may be inspected by FDA every three to five years. Shellfish, which is responsible for 21 percent of all reported foodborne illness that results from the consumption of meat, poultry and fish, is not subject to mandatory inspection. These are only a few examples of inconsistencies in inspections in the present system.

A National Academy of Sciences committee has recommended that the frequency and intensity of inspection be based on the risks presented by the particular food. They have stated that the risk should be determined by analyzing the risk in a manner that takes into account the hazards associated with the food product, the process by which the product is manufactured, and the compliance history of the establishment producing the product. They propose that this could allow federal agencies responsible for food protection to use their resources more efficiently.

4) The present food protection network has inconsistent enforcement authority.

FDA in particular lacks necessary enforcement authorities to assure a safe food supply. Most of FDA's findings of insanitary conditions or practices, or adulterated products, must be resolved through "voluntary" compliance. At times, FDA must attempt to gain legal control of suspect products by use of a federal court warrant. This can be a lengthy process. While the inspector is obtaining the warrant, the products may end up in the market place, unless the states in which the products are located use their authority to seize and detain the hazardous

products. FDA does not have immediate authority to detain adulterated food products. Under the Food, Drug and Cosmetic Act, it lacks the authority to recall adulterated product from the market place, access company safety and quality control records, and preapprove food labels, to prevent fraudulent claims. FDA also lacks authority for a mandatory requirement for the registration of all food producing establishments which it is required by law to regulate. Establishments that are not somehow identified by the agency go uninspected. Too often identification follows the report of a food protection problem. The Food Safety and Inspection Service does have the above authorities, but lacks the authority to prevent the shipment of animals, known to be infected or to bear toxic substances in their tissues, to the plant for slaughter.

5) Food safety research¹⁴ is driven by varying missions from the many agencies for which such research is funded.

A January 1993 report by the Committee on Food, Agriculture, and Forestry Research of the Federal Coordinating Council for Science Engineering, and Technology reports that some 21 Federal agencies spend approximately 200 million dollars on food safety research under approximately 50 laws that directly or indirectly authorize such research. These agencies are within the Department of Health and Human Services, Department of Agriculture, Environmental Protection Agency, Department of Defense, Department of Commerce, National Science Foundation, Department of the Treasury, Department of State, and the National Aeronautics and Space Administration. The research may be basic or applied, laboratory based or social studies research. It may be broadly or specifically focused, and may be carried out in federal laboratories, through contracts, cooperative programs, or grants to academia and the private sector.

The areas or categories of research include microbiology and disease agents, drug and pesticide residues, food additives, natural toxins, environmental and industrial contaminants, food product processing, storage and packaging, diet and nutrition, and food production from preharvest to harvest. Each area of research may address improved methods to identify hazards, prevention and control of foodborne diseases, mechanisms of action of disease agents, risk assessment and risk management methods, or consumer behavior studies.

There is a great need for providing a single food protection agency with the principal authority and responsibility for food safety research. This would eliminate the duplication of expensive research projects, focus research priorities on critical current or emerging problems, develop improved strategies and methods for inspection control, and facilitate effective communications and sharing of information between researchers.

6) The current protection system results in overlapping and duplicate inspections.

Inspection efforts are poorly coordinated. Coordination agreements, under which agencies are required to notify responsible agencies of plant problems or deficiencies found during inspection, do not insure that food safety problems are corrected. A recent GAO report states that insanitary and other unacceptable conditions persist in food processing plants because notifications do not always take place, or problems referred to the responsible agency are not always promptly investigated. A barrier to the effective use of interagency agreements has been a lack of resources, within some agencies, needed to follow up once referrals have been made. Such agencies also lack adequate internal processes for assigning and tracking reported problems. GAO reports products under FDA's authority that are also processed under other agencies' oversight, or fall under other agencies' voluntary inspection or grading programs which are often duplicative and responsibilities are overlapping.

Past efforts to correct deficiencies in the food protection system have failed because the agencies have continued to operate under different regulatory approaches. The division of responsibility between USDA and FDA "has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex. There is no rationale, other than a historic one, to justify maintaining two separate, inconsistent, and costly systems for inspecting and otherwise regulating production of processed foods" reported the Senate Committee on Governmental Affairs in 1977. A new structure defining a food protection agency whose operation would be based on a uniform enforcement authority and a careful evaluation of the risks different food products, food manufacturers, and manufacturing processes pose to the public would enable Congress to enact legislation, fund and oversee a single food protection agency with the capability and credibility required for this essential public service.

Recommendations

Create a single food safety agency responsible for administering a uniform set of scientifically based foods safety laws.

The President and the Congress must establish a new, single food safety agency responsible for protecting the nation's food supply. This agency should be independent and not within the departments that presently exist. The authority for enforcing all federal food inspection laws and regulations, and all personnel, facilities and equipment used by such programs should be transferred to the new agency. The location of the new agency within the Executive Branch of government must be such that the Congressional committees responsible for the appropriation of its funds are unlikely to be those which have a special interest in promoting the inspected industries.

The current laws regulating federal food inspection must be reviewed immediately to identify areas where changes in the laws are needed to base food inspections on sound science and strengthen regulatory authority. The new agency should also begin a review of the current regulations governing federal food inspection for the purpose of producing uniform regulatory requirements, taking into consideration the inherent risk in the product or its production and the unique nature of the foods and the industries that produce them. It is also imperative that the new agency begin immediate studies to determine the program objectives that are to be addressed in order to have the maximum preventive impact on problems of food safety.

An immediate study should be made by the new agency of current staff and resources and the policies governing their utilization, and the information obtained should be used to construct a new organizational structure, a management system, inspection procedures, and research program capable of meeting public health based objectives.

This new food safety agency must serve as a reinvention model. Its primary mission must be consumer protection and food safety. It must be customer driven, listening to and meeting the needs of the consumer within the boundaries of sound science. Prevention of foodborne illness and prevention of poor sanitation and manufacturing practices must replace crisis management. A management system must be in place that strives for continuous

improvement, concentrating on the continuous reduction of risks of foodborne illness. This must include continuous evaluation and reduction in the numerical regulatory standards for sanitation, microorganisms, and residues that assist in reducing risks. Empowering the front line food inspector and eliminating cumbersome layering and complicated chain-of-commands must be accomplished in order to simplify decision making in the field and improve regulatory effectiveness.

User fees should be required for services beyond normal inspection functions. They should be required when food establishments require additional inspection enforcement effort due to repeated noncompliance with regulations, for diagnostic laboratory testing conducted to release detained or recalled product where there is known or potential contamination of product, for other regulatory activity outside of the normal monitoring or surveillance sampling functions, for overtime and additional shifts requiring inspection oversight, inspection of imported food products, certification of exported food products, agency responses to FOIA (Freedom of Information Act) requests, and for other special services as appropriate.

The single food safety agency would eliminate the need for interagency agreements for coordinating inspection activities between agencies, and will eliminate duplicative inspections in establishments with similar products under the authority of different agencies.

It is recommended that the new Food Safety and Inspection Administration meet the following criteria:

1) Existing food safety laws should be amended to provide uniform regulatory authority that is adequate to monitor and control foodborne health hazards at any point in the country's food production system. Animal feeds must be amenable to the laws in order to prevent the adulteration of meat with foodborne disease agents that may originate in such feeds.

This agency must have authority over all food products. The definition of the term "food" must include meat, poultry, milk, eggs, fish, shellfish, fruits, vegetables, grain and grain products, nuts, bottled water, alcoholic and other beverages, any other items eaten by humans, and animal feeds. For meat and poultry products, this definition must include all

wild and domestic animals that are prepared commercially for food. It is imperative that the food protection agency be given sufficient authority to adequately protect consumers from unsafe products and fraud. The laws should give the agency authority to seize, detain, or embargo suspected diseased or contaminated food animals, adulterated products, or food ingredients, order recalls of potentially unsafe products, and have access at any time to industry quality control, food safety, product inventory, and procurement and shipping records. Authority must be provided to require the registration of all food preparation, storage, and shipping establishments.

It is imperative that the agency have criminal prosecution authority, authority to impose civil penalties, and authority to terminate operations, as appropriate. Authority should be provided to identify and control eminent health hazards from the farm to the point of delivery to the consumer. For meat and poultry products in particular, authority to require an identification system, that allows the tracing of the animal to its original source with full authority to take whatever action is needed to eliminate a potential health hazard, is essential. Authority should also be granted to destroy products offered for importation, at U S ports of entry, when such products are known to be hazardous to health or adulterated. Authority should also be provided for the agency to expend funds for education, and consultative assistance to food industry members for the purpose of encouraging the effective use of industrial control systems, such as HACCP, to promote the production of wholesome, unadulterated food. Authority should be provided to the agency to make public its information on the compliance records of food industry members, and the identity of food industry members who are consistent violators of food laws, and to assess user fees from food industry organizations that require special enforcement oversight due to repeated regulatory noncompliance.

2) Qualification standards should be required for the agency to assure that each position that requires final decisions that create or carry out preventive medicine policies be filled only by individuals with the appropriate scientific qualifications.

Without such requirements, persons without the knowledge and understanding required to make decisions that affect the health, and even the life of consumers, may be hired or

promoted to critical positions within the agency. Persons leading the agency, and those who make such important decisions within the agency, must be required to have the medical and scientific educational qualifications and experiences necessary to make sound decisions that are based on the current knowledge of relevant medical and food science.

3) The location of the new agency, within the Executive Branch, must be such that the Congressional committees responsible for oversight and the appropriation of its funds are those whose principal concerns are the health and economic welfare of this countries citizens, and not those whose principal interests are in the economic welfare of the producers of food or the inspected food industries.

The credibility of the current food protection programs has suffered greatly from the well known influence of the food industry, and its political advocates, on agency policy and day-to-day inspection activities. It is of utmost importance that the consuming public be assured that the protection of their food supply from health hazards or economic fraud is the first and foremost objective of the agency, and that all policies are made and inspection activities are carried out with that goal in mind. The ability to carry out a program that is scientific and objective in nature, free of coercion from within the funding or oversight process, is critical to the success of this agency.

4) All food safety research functions must be included in the single food safety agency.

All food safety research, both basic and applied, must be "mission driven" and have a "protected" budget that prevents its diversion from its research program. It should be shown as a separate and independent line item within the agencies budget. The agency should have authority to both conduct appropriate research within the agency and to contract for research with the best available scientific sources for that which it is not staffed or equipped to perform. All data produced by approved research should be published, after appropriate peer review, without editing by the agency.

Research must be employed to identify emerging disease problems and to develop improved strategies and methods for the control or prevention of current and emerging food

protection problems. Control strategies must be compared to weigh their effectiveness and cost efficiency for carrying out their intended objectives

The working group is confident that a new, single, independent food safety agency could successfully administer a scientific, uniform set of food safety laws, and provide the consumer with a regulatory system that is cost efficient and capable of protecting the nation's food supply.

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CRS Report for Congress

Selected Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1949-1993

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SELECTED RECOMMENDATIONS FOR CHANGES IN THE FEDERAL ORGANIZATION OF FOOD SAFETY RESPONSIBILITIES, 1949-1993

SUMMARY

This report summarizes eighteen recommendations, made in the last five decades, for changing the Federal organization of food safety responsibilities. Since 1906, food safety responsibilities and inspections have been split by product under different laws. Congress passed the Pure Food and Drugs Act on June 30, 1906 and the Meat Inspection Act to take effect on October 1, 1906. Both Acts placed the responsibility in the U.S. Department of Agriculture (USDA). Over time, USDA kept responsibility for meat safety, while most other foods became regulated by the Food and Drug Administration (FDA) of the Public Health Service.

Recommendations for changing the Federal food safety system appear to fit into one of three categories. The recommendations proposed that: 1) a single independent food safety institution be given responsibility for all food safety; 2) responsibility for all food products should be returned to USDA; or 3) responsibility for all food products should be given to FDA.

Most of the recommendations had both supporters and critics. If all food safety responsibility were given to a single independent agency, supporters claim that this agency could promulgate consistent regulations and inspections for all foods, whether meats or canned foods, thereby increasing the confidence of U.S. consumers in the food supply. Critics claim that a new food safety agency would have tremendous start up costs in a era of tight budgets, and would not take advantage of the long-term experience and regulatory organization developed by USDA and FDA.

If all food safety responsibility were given to USDA, supporters feel that USDA would organize for greater utilization of new research and enforcement techniques. Critics claim that it is not possible for one agency to promote products and remain at an arm's length distance for regulating the same products.

If all food safety responsibility were given to FDA, supporters feel that FDA could use its long-term expertise to regulate consumer products and would be able to set and enforce consistent standards across all foods. Critics argue that FDA is not organized to regulate all foods and would have to completely change its orientation perhaps being overwhelmed by the process.

TABLE OF CONTENTS

INTRODUCTION	1
BACKGROUND	1
CURRENT FEDERAL FOOD SAFETY RESPONSIBILITIES	7
OVERLAPPING RESPONSIBILITIES	8
RECOMMENDATIONS FOR CHANGES IN THE FEDERAL ORGANIZATION OF FOOD SAFETY RESPONSIBILITIES	9
FOOD SAFETY UNDER A SINGLE, INDEPENDENT AGENCY	11
GAO Food Inspection Report, 1970	11
White House Conference on Food, 1970	13
Ralph Nader Report, Sowing the Wind, 1972	14
Hearings on S. 3419, Consumer Safety Act of 1972	15
GAO's Risk-Based Inspection Report, 1992	16
The Durenberger Food Safety Bill, 1993	17
Carol Tucker Foreman, Safe Food Coalition, August 17, 1993	18
FOOD SAFETY UNDER THE U.S. DEPARTMENT OF AGRICULTURE	20
The Hoover Commission Report, May 20, 1949	20
Restructuring of Meat and Poultry Products Inspection ...	22
FOOD SAFETY UNDER THE FOOD AND DRUG ADMINISTRATION	24
HEW Reorganization Order of March 1968	24
The Malek Report, December 10, 1969	25
The Ash Council Report of January 1971	26
Senate Governmental Affairs Report on Federal Regulations, 1977	27
President Carter's 1978 Government Reorganization Project or White House Study	28
Dr. Lester Crawford, 1980	29
Dr. Sanford Miller, 1989	30
The Edwards FDA Advisory Committee, May 1991	31
National Performance Review, September 1993	33
TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1993	34

SELECTED RECOMMENDATIONS FOR CHANGES IN THE FEDERAL ORGANIZATION OF FOOD SAFETY RESPONSIBILITIES, 1949-1993

INTRODUCTION

At times, consumers have questioned whether the Federal organization of food safety is "good enough" or whether a different system may better serve consumer needs. Consumer questions often revolve around which standards are used when judging whether food is considered safe, and what type of organization should the executive branch of the Federal Government have to respond to these consumer concerns. Throughout the past five decades, the executive branch and Congress have considered recommendations for changes in the Federal organization of food safety.

This report lists several recommendations given to the President or to Congress to change the structure of food safety responsibilities. These recommendations were made by groups inside and outside the Federal Government and all have contributed to the debate over food safety through the years. The list of selected recommendations comes from various Presidential commissions and study groups, the U.S. General Accounting Office, congressional committees, prominent food policy spokespeople in speeches, and in proposed legislation between 1949 and 1993. Some recommendations were also found in articles or books cited at congressional hearings, and appear to have influenced the debate on the restructuring the Federal organization of food safety.

BACKGROUND

Two executive branch agencies, the U.S. Department of Agriculture (USDA) and the Public Health Service (PHS), have held the responsibility for implementing the laws and regulations for food safety within the Federal Government. The Federal Government's role in food safety began to increase when, at the turn of the century, developments in transportation systems increasingly brought processed food into growing cities. The residents of these cities lost the ability that villagers had possessed of being first-hand judges of the food they ate. U.S. consumers began questioning the safety of what they were buying in stores. The chief chemist of USDA, Dr. Harvey W. Wiley tested food preservatives with his famous "poison squad" and provoked interest in food safety throughout the country. The time was ripe for reform, and, under pressure from certain consumer groups and from President Theodore Roosevelt, Congress passed the 1906 Food and Drugs Act on June 30, 1906. This Act set up the regulatory role of the Federal Government for foods other than meat and

poultry by prohibiting from interstate commerce food and drugs that were adulterated and/or misbranded. Adulteration in the act was defined as:

...generalities proscribing the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products.¹

Misbranding meant placing false or misleading statements on the label. Yet, food safety involved more than these two concepts. The 1906 Food and Drugs Act also had provision for enforcement for it required that adulterated foods not only be seized, but also destroyed.

In 1905, Upton Sinclair published *The Jungle*, a book about the way meat was handled in the Chicago's slaughterhouses. It had a major impact on Members of Congress and their constituents and led to the passage of the Meat Inspection Act of 1906 (P.L. 59-242), which set standards for slaughter and meat sold in interstate commerce.² It established sanitary standards for slaughter and processing facilities. With the passage of the 1906 Meat Inspection Act, in an appropriations bill for USDA, USDA began a system of continuous daily inspection of all meats in slaughterhouses. Inspectors used organoleptic (sight, smell, touch) means to detect problems and could instantly condemn carcasses.

The 1906 Food and Drugs Act placed the emphasis on chemical problems and USDA officials of the Bureau of Chemistry worked on laboratory detection methods of pathogens. During the 1920's, conflicts sometimes occurred between USDA officials who supported producers and those regulators who were charged with enforcing various standards, particularly chemical standards, and who were concerned about food adulteration. At the time, California apple growers used large quantities of arsenic on apples to fight pests. USDA had

¹Lauffer Hayes and Frank Ruff, the Administration of the Federal Food and Drugs Act. In Hutt, Peter Barton and Richard A. Merrill. Food and Drug Law: Cases and Materials. 2nd ed. Westbury, New York, The Foundation Press, Inc., 1991. p. 9.

²Meat had been separated from other food for special legislative treatment in 1890 and 1891. Federal inspection began as a means of reassuring European nations that U.S. meats were safe. Europe had banned imports of U.S. pork on the charge that it had caused epidemics of trichinosis. A newspaper scare arose during the Spanish-American War when U.S. packers were blamed with shipping "embalmed beef" that sickened the troops. Investigation attributed some of the trouble to the rapid growth of bacteria in meat exposed to the hot Cuban sun. Young, James Harvey. The Long Struggle for the 1906 Law, FDA Consumer, v. 15, no. 5, June 1981. p. 16.

CRS-3

developed a limit for the maximum amount of arsenic residue that could be left on the fruit. Some of the apples had residues that exceeded this limit. This conflict in mission had begun in the early part of the century. The following statement characterizes the conflict:

The Bureau of Chemistry [of FDA] had originated as a research bureau and law enforcement was a superimposed responsibility. The task of undertaking research designated to improve the methods of utilizing agricultural products was frequently in striking conflict with enforcement of the Pure Food and Drugs law. These conflicts arose, first, because there was a constant tendency to stop a research project so as to permit the scientist to assist in acquiring evidence immediately needed in a lawsuit and second, because the objectives of law enforcement frequently did not coincide with increasing the utilization of a particular agricultural product, but instead might retard its utilization.³

One part of the agency which was supporting producers had different responsibilities from the other regulatory part of the agency.⁴

In 1927, Dr. Walter Campbell of U.S. Department of Agriculture's (USDA) Bureau of Chemistry recommended that the Secretary of Agriculture separate the functions of agricultural research from the enforcement functions. Congress had charged USDA with other enforcement functions in several acts.⁵ He suggested the Secretary create a Food, Drug, and Insecticide Administration (FDIA) within the Department. Congress supported this suggestion and in the 1927 appropriations bill created the FDIA to enforce the 1906 Pure Food and Drugs Act.⁶ Simultaneously, the Secretary created a soil and chemistry bureau that would handle research functions. In 1930, USDA dropped the insecticide from this agency's title so its name became the Food and Drug Administration (FDA).

FDA's new enforcement and research responsibilities continued to grow as did the agency's commitment to consumer protection. In 1930, Congress passed an act setting standards for canned foods that excluded meat and milk

³Brannon, Michael. Organizing and Reorganizing FDA. Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law. Food and Drug Law Institute Series. Edited and published by the Food Drug Law Institute. Washington, D.C., 1984. p. 142.

⁴Telephone conversation with Suzanne White, History Office, Food and Drug Administration. October 18, 1993. (301) 443-6367.

⁵Laws included: Food and Drugs Act, the Insecticide Act, Caustic Poison Act, Naval Stores Act, Import Milk Act, Filled Milk Act, and Import Tea Act.

⁶Whitnah, Donald R. ed., Government Agencies. Westport, CT, Greenwood Press, 1983. p. 251.

CRS-4

products. As the New Deal began in 1933, pressures mounted to pass a new law that would remedy the gaps in the 1906 Pure Food and Drugs Act. A tragedy occurred in 1937 that resulted in strengthening the Federal role of pre-market review of drugs and other matters. At least 73, and perhaps over 90, persons died as a result of taking "Elixir Sulfanilamide." Franklin Roosevelt's son had recovered from a fatal infection using sulfanilamide, a European wonder drug. Problems developed not from the drug itself, but in the solvent solution used to dissolve the drug. The poison was diethyleneglycol, a solvent employed without toxicity testing in a liquid form of sulfanilamide. The disaster prompted amendment in 1938 of the law that required manufacturers to prove a drug's safety to FDA before marketing it. Consumers began to support the idea that there should be Federal pre-market approval for both drugs and substances added to foods.

On June 25, 1938, President Roosevelt signed into law the Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) that today remains the leading authorizing legislation for food safety. Up to that time, USDA had had primary responsibility for food safety for almost 80 years. The law gave authority to the executive branch for the regulation of livestock and poultry feeds and drugs used in animal disease control. After the 1938 law was passed, President Roosevelt said:

"The work of the Food and Drug Administration is unrelated to the basic function of the Department of Agriculture," and he expressed his belief that "the opportunity for the Food and Drug Administration to develop along increasingly constructive lines" lay in the Federal Security Administration.⁷

The Act gave FDA the authority to test for the safety of new products. In 1940, because of the added research and testing responsibilities given the Food and Drug Administration by the FFDCA, the President moved FDA out of USDA and into a separate part of the executive branch, the Federal Security Agency (FSA). At the time, the FSA mission was to protect the public health and it had under its jurisdiction the Public Health Service, the Office of Education, the Civilian Conservation Corps, and the Social Security Administration, among other agencies. FSA was a new agency; it had been in existence for only one year. FDA's responsibilities under the FSA included regulating food quality, sanitation, and consumer protection. It focused on the issue of whether a given substance in foods was "poisonous or deleterious" within the meaning of section 406 of the statute. As an operational rule, FDA sought to ban any substance that was toxic in laboratory animals at one percent or less in the diet.

Not everyone agreed with the President's decision about reorganizing FDA. Secretary of Agriculture Henry A. Wallace argued that the meat inspection work of USDA's Bureau of Animal Industry also should be transferred. He claimed:

⁷Brannon, *Organizing and Reorganizing FDA*, p. 158.

CRS-5

This activity might be associated with other health or public welfare work. Meat inspection is of course a technical job and it seems logical to have the technical inspectors attached to the bureau most competent in this field.⁸

However, President Roosevelt was not persuaded; meat and poultry inspection remained within USDA. The USDA meat inspection system had developed on a parallel track with the Bureau of Chemistry within USDA for over 50 years. It used veterinarians trained in spotting animal diseases for daily inspection of animals before slaughter and examination of each carcass for disease and contamination after slaughter. The system appeared to work for the United States was well positioned to supply meat to the world during World War II.

The war effort was not confined to USDA. Even after FDA was transferred out of USDA, FDA was charged with ensuring the enrichment of breads in 1942 for the soldiers serving in World War II. Several years later (1953), the FSA became the Department of Health, Education, and Welfare. In 1968, FDA became part of the Public Health Service where it added a focus on health and nutrition to food safety.⁹

Since the start of Federal regulation, food safety has been the primary responsibility of only two different cabinet agencies, USDA and DHHS. The following chart shows which statute and consequently which department was responsible for carrying out the statutes' mandates on food safety since the Federal Government became involved.

⁸Memo to President Franklin D. Roosevelt from Henry Wallace, April 20, 1939. Found in U.S. Congress. Senate. Committee on Governmental Affairs. Study on Federal Regulation. Senate Document no. 95-91, 95th Cong., 2d sess. v. V. Regulatory Organization. Dec. 1977. p. 140.

⁹Telephone conversation with Suzanne White, History Office, Food and Drug Administration. October 18, 1993. (301) 443-6367.

**CHART 1. Institutional Chronology of Food Safety Responsibilities,
1862-1993**

YEARS	STATUTE	NAME	DEPARTMENT
1862-1890		Chemical Division	U.S.Department of Agriculture (USDA)
1890-1901	Act of March 3, 1891 and Act of March 2, 1895 on exported meats	Division of Chemistry	USDA
1901-1927	1906 Pure Food Act 1906 Appropriations Act	Bureau of Chemistry and Bureau of Animal Industry	USDA
1927-1930		Food, Drug, and Insecticide Administration	USDA
1930-1940	1938 Federal Food, Drug, and Cosmetic Act (FFDCA)	Food and Drug Administration	USDA
1940-1953		Food and Drug Administration	Federal Security Agency
1953-1970	1954 Miller Pesticide Act and 1958 Food Additives Act (Delaney Clause)	Food and Drug Administration	Department of Health, Education, and Welfare
	1958 Humane Slaughter Act; 1967 Wholesome Meat Act; 1968 Poultry Products Act	Meat Inspection Branch of Agricultural Research Service	USDA
1970-1979	Reorganization Plan No. 3 of 1970; sect. 346, 346a, 348, and 408 of FFDCA and 135-135k of FIFRA	all pesticide regulation responsibilities were transferred to EPA	Environmental Protection Agency (EPA)
		Transfer of all functions of Environmental Quality Branch, Plant Protection Division of Agricultural Research Service to EPA	EPA
	1972 Meat and Poultry Inspection	Animal and Plant Health Inspection Service	USDA
1979-		Food and Drug Administration	Department of Health and Human Services

Source: Hutt, Peter Barton. and Richard A. Merrill. Food and Drug Law: Cases and Materials. 2nd ed. Westbury, New York, The Foundation Press, Inc., 1991. p. 4-5; other materials.

CURRENT FEDERAL FOOD SAFETY RESPONSIBILITIES

Historically Congress passed laws to resolve immediate food safety problems. These laws assigned food safety responsibilities to several executive departments. Today the key roles are played by the Food and Drug Administration (FDA) under the Secretary of the Department of Health and Human Services (DHHS), and the Food Safety and Inspection Service (FSIS) under the U.S. Department of Agriculture (USDA). Together these two agencies, and several others, try to ensure that food products, as sold in the United States, will not adversely affect human health.

FDA is part of the Public Health Service under DHHS and is charged with ensuring that foods (except meat,¹⁰ poultry, and egg products) are safe, nutritious, sanitary, wholesome, and not adulterated or misbranded (mislabelled). A food is considered adulterated if it contains substances that may render it injurious to health. FDA carries out these responsibilities for the most part under the authority of the Federal Food, Drug, and Cosmetic Act (FFDCA).¹¹

USDA is responsible for monitoring meat, poultry, and egg products under the Federal Meat Inspection Act, as amended, and the Poultry Products Inspection Act, as amended. The Food Safety and Inspection Service (FSIS) of USDA is directly responsible for the daily inspection of all meat and poultry entering U.S. commerce.

In total, twelve agencies in Federal and State governments have food safety responsibilities.¹² Besides FDA, the Centers for Disease Control and Prevention (CDC) under DHHS investigates foodborne illnesses and diseases. Other agencies besides FSIS within USDA are the Agricultural Marketing Service (AMS) which inspects and grades quality of egg, dairy, fruit, vegetable, meat, and poultry products; the Agricultural Research Service (ARS) which performs food safety research; the Animal and Plant Health Inspection Service (APHIS) which has regulatory programs to protect animals and plants from pests and disease; and the Federal Grain Inspection Service (FGIS) which inspects the quality of grain, rice, and related products.

¹⁰FDA does have jurisdiction over game meat.

¹¹Other relevant statutes are the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, the Public Health Service Act, the Fair Packaging and Labeling Act, as amended, the Federal Meat Inspection Act, as amended; the Poultry Products Inspection Act; Federal Import Milk Act; Plant Quarantine Act, as amended, and the Pesticide Monitoring Improvements Act.

¹²Detailed information on these responsibilities can be found in U.S. General Accounting Office. Food Safety and Quality: Who Does What in the Federal Government. Report to Congressional Requestors. GAO/RCED-91-19A and 19B, Dec. 1990. .

CRS-8

The Environmental Protection Agency (EPA) regulates pesticides and is charged with setting pesticide residue tolerances for each pesticide/food combination. The Bureau of Alcohol, Tobacco, and Firearms (BATF) of the U.S. Treasury, regulates production, distribution, labeling of alcoholic beverages, and the U.S. Customs Service of Treasury examines and collects food import samples for other Federal agencies, particularly FDA. The National Marine Fisheries Service (NMFS) of the U.S. Department of Commerce conducts a voluntary seafood inspection program and is working closely with FDA on developing a new approach to seafood inspection. The Federal Trade Commission (FTC) regulates advertising of food products.

OVERLAPPING RESPONSIBILITIES

Over time the various responsibilities for food safety have been split among different Federal agencies with different missions. A natural tension is created when research and promotional goals of Federal agencies compete for attention with their enforcement responsibilities.

Critics charge that part of the "food safety problem" is that U.S. food safety laws and regulations are fragmentary, inconsistent, and too many agencies are responsible for food safety activities. Foods posing similar health risks can be inspected by different agencies at different frequencies. For example, the USDA inspects pepperoni pizza processors daily, while the FDA inspects cheese pizza processors every three to five years.¹³ Some appear to believe that it is inappropriate for the Nation's food supply to have separate agencies with completely separate standards governing the safety of different parts of the U.S. food supply.¹⁴ Others think that the tensions created by different systems have resulted in a safer food supply.

Others charge that safety cannot be properly regulated when its responsibility is placed in the hands of the same agency in charge of promoting regulated products. For example, meat and poultry promotion as well as inspection are the responsibility of FSIS. Many think that an organization that promotes and subsidizes production agriculture and other consumer products should be separate from one that watches over their safety.

Over time the definition of "food safety" has expanded and come to signify certain responsibilities regarding foods. The responsibilities were aptly defined in an FDA report to Congress:

¹³Leonard, Rodney E. A Single Food Safety Agency. Nutrition Week. Community Nutrition Institute. v. XXIII no. 34., Sept. 10, 1993. p.2.

¹⁴Telephone conversation with Dr. Sanford Miller, Professor and Dean, Graduate School of Biomedical Sciences. The University of Texas Health Science Center at San Antonio. September 17, 1993. (210) 567-3709.

Under the foods program, FDA sets food standards; evaluates food additives and packaging for potential health hazards; conducts research to reduce food-borne disease to determine specific health impacts of hazardous substances in food and to develop methods for detecting them in foods; and maintains surveillance over foods through plant inspections, laboratory analyses, and legal action where necessary.¹⁶

USDA carries out similar functions for meats, poultry, and eggs.

Whether or not all food should be regulated by the same or different agencies is currently under debate. Some argue that a clearer direction in food safety policy could be derived from a single independent agency charged with administering all food safety programs. Others oppose the formation of a single agency, asserting that the various agencies with differing expertise strike a balance among often divergent interests.

RECOMMENDATIONS FOR CHANGES IN THE FEDERAL ORGANIZATION OF FOOD SAFETY RESPONSIBILITIES

The remainder of this report divides a selected number of recommendations/proposals to change the organization of food safety responsibilities into three loosely constructed categories:

- A. recommendations that suggest a separate single agency approach or some modification of this idea;
- B. recommendations that all food safety functions to be lodged in USDA;
- C. and recommendations that all food safety responsibilities be given to FDA.

Since 1949, 18 separate recommendations have been presented by task forces, committees, and others to change the way in which food safety is ensured for U.S. citizens. Recommendations were selected because they appeared to have some point of view on the organization of Federal food safety. It is not an exhaustive list. Nor do all the recommendations fit neatly into the three categories. Some of the recommendations listed here would only reorganize the food safety functions within the agency where they now lie.

¹⁶U.S. Congress. Senate. Agriculture, Rural Development, and Related Agencies Appropriation Bill, 1990. Senate Rept. no. 101-84, 101st Congress, 2d sess. (1989) as found in Hutt, Peter Barton, and Richard A. Merrill. Food and Drug Law: Cases and Materials. 2nd ed. Westbury, New York, The Foundation Press, Inc., 1991. p. 21.

CRS-10

No President nor Congress has adopted these recommendations. However, the reports and publicity of each has added to the debate and helped to define the current food safety responsibilities. Seven of the recommendations would have created some type of independent entity for the regulation of food safety and would have combined all foods under one entity. Two would have given all responsibility to USDA, and 9 would have FDA reorganize and regulate all food safety including meat and poultry. The most recent proposals appear to be evenly divided between giving food safety responsibility to a single, independent agency or to reorganize FDA and link food safety to public health. Table 1 summarizes in chronological order the selection of recommendations presented to the President and Congress.

Most of the reports or recommendations respond to what is perceived to be four separate problems in food safety and would organize a new food safety structure around these problems:

- First, whether food safety is a public health responsibility only or whether it can be linked with research and development of new standards that not only protect consumers but also develop and market new products.
- Second, whether the cost to the Federal Government would increase or decrease by combining all agencies regulating food into a single food safety agency.
- Third, if Congress and the Administration chose to create an independent food safety agency, whether such an agency would be independent of or located within the Public Health Service.
- Fourth, whether U.S. consumers would be better protected by having a uniform set of regulations and laws that covered all foods and were enforced by a single agency.

Some believe that one agency with responsibility for food safety could regulate consistent and strong food standards which would assist in building public confidence in the Federal system of food safety. Others argue that although some consumers are very vocal in their distress with the current regulatory framework, it does provide some of the safest, most abundant, and least expensive food in the world.

Most believe that pressures for change will continue in the future focusing mainly on streamlining policies for food, nutrition, and veterinary drug activities. There have always been threads that link the different food safety programs with those of production agriculture and with nutrition research.

FOOD SAFETY UNDER A SINGLE, INDEPENDENT AGENCY

Popular Name and Date

GAO Food Inspection Report, 1970¹⁶

Description and Mission of Group Making Recommendations

Comptroller General of the United States. Report to the Congress. Need to Reassess Food Inspection Roles of Federal Organizations. GAO Report B-168966 (June 30, 1970). In a letter to the President of the Senate and the Speaker of the House of Representatives, the Comptroller General of the United States presented the results of a review of the roles of Federal organizations involved in inspecting food. GAO's authority to conduct the review was contained in the Budget and Accounting Act of 1921 (31 U.S.C. 53); the Accounting and Auditing Act of 1950 (31 U.S.C. 67); and the authority of the Comptroller General to examine contractor's records as set forth in 10 U.S.C. 231(b).

Summary of Recommendations and Impact

Federal food inspection evolved from piecemeal legislation and regulations, designed to solve specific problems when they arose, and does not provide a clear expression of an overall Federal policy for food inspection. As a result, parts of the food inspection process are performed by many Federal, State, and local organizations. Such a process has led to some overlap and caused dissatisfaction among the food industry. The dissatisfaction comes from inspections being made for different purposes and varying in degree. Also, agreements made between these organizations to establish clearer lines of responsibility make more effective use of the skills and experience of each and reduce overlap. But these agreements are time consuming to arrange and difficult to administer.

Although the report did not specifically recommend consolidation, it criticized the overlapping inspection activities among USDA, FDA, and other Federal agencies and the lack of consistency in their requirements, procedures, and concepts. GAO recommended that the Director, Bureau of the Budget, make a detailed evaluation of the Federal food inspection system to see how to improve its administration and determine if it is feasible to consolidate some of the inspections.

¹⁶U.S. General Accounting Office. Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health, Education, and Welfare, Department of the Interior. Report to the Congress by the Comptroller General of the United States. Rept. no. B-168966. June 30, 1970.

Dissenting Views

Most of the Federal agencies responsible for food inspections agreed with the recommendation for an evaluation. USDA's comments implied that GAO had not properly characterized certain USDA inspection functions. In its response letter, as published in the GAO report, it stated:

Meat inspection, for example, is looked upon primarily as a program for consumer protection or benefit. This it is, but we believe it also facilitates interstate commerce in meats and enhances the market for farm animals sold for meat. Similarly meat grading, while it may be primarily looked upon as a program for facilitating marketing or dealing in meat, is recognized by consumers as a purchasing tool and, we believe as well, benefits the farmer by giving him added assurance of a return related to the quality of the animals sold. On the other hand, the consumer benefits from grading of grain are quite indirect. Performance standards are designed to be uniform whether the service is mandatory or voluntary. Thus procedures and regulations are geared to the particular need. The consumer's interests are expected to be recognized and protected in each case. It is the needs, and not whether the primary beneficiary is the producer, consumer, or industry that determines requirements and methods.

*Popular Name and Date***White House Conference on Food, 1970¹⁷***Description and Mission of Group Making Recommendations*

President Nixon asked a large group of experts to meet and make recommendations on revising the Federal regulatory policy for food and on certain aspects of food, nutrition, and health policy. He requested recommendations regarding administration and operations, community affairs, information and education. The Conference was chaired by Dr. Jean Mayer and his deputy chairman, James D. Grant.

Summary of Recommendations and Impact

The Conference recommended that there should be one Federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods. The Conference also recommended that the Secretary of HEW issue an order establishing a separate interdepartmental coordinating committee on Federal food regulatory policy. The committee would be comprised of representatives of all Federal departments and agencies having jurisdiction over safety, sanitation, identity, and labeling of any food. Within certain schedules, the committee should issue reports on the progress of reconciling all pertinent Federal food policies and practices. The committee should initially consider the question of whether a single Federal regulatory agency for foods should be established, and particularly whether the jurisdiction of USDA over food products derived from or utilizing inspected meat and poultry should be transferred to HEW.

Dissenting Views

Not Available

¹⁷White House Conference on Food, 1969. White House Conference on Food, Nutrition, and Health. Final Report. Washington, D.C., 1969.

Popular Name and Year of Document

Ralph Nader Report, Sowing the Wind, 1972.¹⁸

Description and Mission of Group Making Recommendations

This report was sponsored by the Center for Study of Responsive Law, and was conducted by an interdisciplinary task force of young professionals trained in law and science. Its members engaged in administrative, legal, and congressional proceedings on a wide range of issues from the fat and chemical content of hot dogs to the potential birth defect hazards of pesticides. Ralph Nader wrote the introduction to the report. The report had some influence on consumer opinion about certain food hazards.

Summary of Recommendations and Impact

Found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommends that meat inspection and chemical monitoring in USDA and the food inspection functions of FDA, should be transferred to a new food safety agency where the goal of protecting public health would be consolidated. It also suggested that food inspection be included in the responsibilities of the independent "consumer safety agency" under consideration at the time in Congress.

Dissenting Views

Not Available

¹⁸Wellford, Harrison. *Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest*. New York, Grossman Publishers, 1972. p. 354.

*Popular Name and Date***Hearings on S. 3419, Consumer Safety Act of 1972.¹⁹***Description and Mission of Group Making Recommendations*

A series of three separate hearings were held in the Senate about the proposed restructuring of food safety responsibilities in the Federal Government. The Commerce Committee held a hearing on April 13, 1972. A hearing was held by the Subcommittee on Executive Reorganization and Government Research of the Government Operations Committee on April 20, 21, May 2, 3, 1972. Hearings before the Subcommittee of Health of the Labor and Public Welfare Committee on May 2, 3, 1972 all considered S. 3419, the Consumer Safety Act of 1972.

Summary of Recommendations and Impact

The Consumer Safety Act of 1972 provided for the transfer of HEW functions administered through FDA, such as food and drugs, and the Division of Biologics Standards (DBS) and other product safety functions of the Department of Commerce and the Federal Trade Commission to the independent Consumer Safety Agency to be created by S. 3419. The purpose was to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death. S. 3419, became the umbrella legislation and was called the Food, Drug, and Consumer Product Safety Act of 1972. It passed the Senate on June 21, 1972.

Dissenting Views

The Administration had thought that the establishment of an independent consumer safety agency could prove to be regressive rather than progressive. On March 16, 1972, in a press release on S. 3419, Secretary of Health, Education, and Welfare Richardson stated:

I think...that if the Food and Drug Administration is going to have any problems of digestion of new responsibilities, the problems would be multiplied several fold by the effort to create a new agency duplicating administrative authorities and having to seek scientific capabilities and resources that are already within the Food and Drug Administration. ... It is ... much greater if we build upon the experience and capabilities of the Food and Drug Administration, than if we start all over again through the creation of comparatively small, isolated outside body.

¹⁹U.S. Congress. Senate. Report of the Senate Commerce Committee. S. Rpt. 92-749; Senate Government Operations Committee. Hearings. Senate Labor and Public Welfare Committee. Hearing. S. Rpt. 92-835.

CRS-16

*Popular Name and Date***GAO's Risk-Based Inspection Report, 1992.²⁰***Description and Mission of Group Making Recommendations*

In a response to a request from the Honorable John D. Dingell, Chairman Subcommittee on Oversight and Investigations, House Committee on Energy and Commerce, GAO published a report entitled Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply in June 1992.(GAO/RCED-92-152) Its mandate was to examine the consistency, efficiency and effectiveness of the Federal food safety inspection system.

Summary of Recommendations and Impact

GAO found that 12 agencies, (see page 4 above) that were involved in food safety, inspect similar foods posing similar risks at inconsistent frequencies and under different enforcement authorities. It also found long-standing problems whereby these agencies use their inspection resources inefficiently and do not effectively coordinate with each other. GAO recommended that "Congress hold oversight hearings to evaluate options for revamping the federal food safety and quality system including creating a single food safety agency responsible for administering a uniform set of food safety laws."

Dissenting Views

DHHS responded to this GAO report by stating that there was no reason to believe that creating a new single agency would improve basic food safety. FDA, through DHHS, suggested that: 1) it can formally establish regulations without new legislation which can, for the most part, address the nature and extent of problems encountered by the food production industry; 2) the food industry can be held accountable for self-regulation to a even greater degree than presently implying that an independent agency is unnecessary; and 3) a policy can be established through regulation which compares risks. In addition, FDA claimed that the GAO report had failed to mention or analyze some major issues for the food industry. These issues include: 1) whether the food industry needs uniformity in regulations by States and international harmonization of standards among countries; 2) whether market promotion activities should be commingled with safety regulation; and 3) whether the potential impact of new food technologies both in producing and developing new and novel foods, would affect how regulations can ensure food safety.

²⁰U.S. General Accounting Office. Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply. GAO/RCED-92-152. June 1992.

*Popular Name and Date***The Durenberger Food Safety Bill, 1993.²¹***Description and Mission of Group Making Recommendations*

On August 3, 1993, Senator Durenberger introduced S. 1349, the Food Safety and Inspection Agency Act of 1993 and it was referred to the Senate Committee on Governmental Affairs. So far, there have been no hearings.

Summary of Recommendations and Impact

The act, if passed, would place all food safety and inspection activities in a single, independent agency which would, with the guidance of a 15 person expert commission, set uniform risk-based inspection standards by which food safety would be ensured. It would also establish a State-Federal communications network to educate consumers on potential microbial diseases.

Dissenting Views

Some critics claim that the act does not clearly define what a uniform risk-based safety system is, nor how the current two separate field inspection systems would be organized.

²¹S. 1349 was introduced by Senator Durenberger on August 3, 1993.

Popular Name and Date

Carol Tucker Foreman, Safe Food Coalition, August 17, 1993.²²

Description and Mission of Group Making Recommendations

These recommendations in the form of a policy proposal, reflect support from the American Public Health Association; Center for Science in the Public Interest; Consumer Federation of America; Consumers Union; Food and Allied Service Trades, AFL-CIO; Government Accountability Project; National Consumers League; Public Citizen; Public Voice for Food and Health Policy; United Food and Commodity Workers International Union.

Summary of Recommendations and Impact

The proposal recommends that the Clinton Administration combine all food safety programs within DHHS. The proposal would combine all food inspection in a new agency and elevate FDA to independent status on a level equal to the Social Security Administration. The proposal supports the June 1992 GAO report recommendation to combine food safety functions and recommends that it be adopted because there appears to be no justification for meat and poultry inspection to be separated from the rest of food inspection. It recommends an independent food safety agency to combine the functions of FDA and USDA and the pesticide programs of EPA with the existing programs of the Consumer Product Safety Commission and the renaming and the reconfiguring of that agency. It would bring together programs and personnel with similar goals and claims it would be an opportunity to reduce administration and personnel costs.

Dissenting Views

Giving the task of regulating meat and poultry to FDA would be similar to "the gnat swallowing the elephant," says Marian Burros in a recent newspaper article.²³ FDA currently has about 1,500 full time equivalent (FTE) positions for all types inspection and sample analysis of foods, whereas FSIS of USDA has about 7,400 FTEs for meat and poultry inspection. The types of inspections are somewhat different from one agency to the other. With extensive scientific training, FDA inspectors take microbial samples for laboratory analysis; they check temperatures in canning processes; they check machinery; and their evaluations and detailed descriptions must be able to support any regulatory action that may lead to a legal proceeding. FSIS has a different approach to inspections. FSIS meat and poultry inspectors rely on constant and daily

²²Safe Food Coalition. Reinventing Meat and Poultry Inspection: Building a Public Health Based Program. August 17, 1993. (202) 822-8060. Telephone conversation with Joy Stevens, FDA, Sept.23, 1993. (301) 443-3793.

²³Burros, Marian. Clinton Plan Would Move Meat and Poultry Inspections to FDA. New York Times, Sept. 13, 1993. p. A18.

CRS-19

organoleptic inspection (based on sight, touch, or smell) of products as they flow by on the assembly line. They can immediately condemn carcasses which do not pass standards. FSIS inspectors also draw and send samples for laboratory tests, review exports and inspect imports, set national standards, and give technical and financial assistance to 26 States.²⁴

²⁴Telephone conversation with Joy Stevens, FDA, September 23, 1993. (301) 443-3793. Telephone conversation with Will Kerr, FSIS Budget Formulation and Presentation Branch, September 24, 1993. (202) 720-2912.

FOOD SAFETY UNDER THE U.S. DEPARTMENT OF AGRICULTURE

Popular Name and Date

The Hoover Commission Report, May 20, 1949.²⁵

Description and Mission of the Group Making Recommendations

Headed by Herbert Hoover, former President of the United States, the Commission on Organization of the Executive Branch of the Government was organized in accordance with Public Law 162, 80th Congress, approved July 7, 1947. It was created by unanimous vote of Congress in July, 1947, and submitted a series of reports to Congress. The Lodge-Brown Act, which brought it into being, conceived of its mission as being bipartisan. Therefore the Commission had six members from each party. Four Commissioners each were chosen by the President of the Senate, the Speaker of the House of Representatives, and President Truman. The Commission members consisted of: Herbert Hoover, Chairman; Dean Acheson, Vice Chair; Arthur S. Flemming; James Forrestal; George H. Mead; George D. Aikin; Joseph P. Kennedy; John L. McClellan; James K. Pollock; Clarence J. Brown; Carter Manasco; James H. Rowe, Jr.

Summary of Recommendations and Impact

The Commission recommended that all regulatory functions relating to food products be transferred to the Department of Agriculture and that those relating to other products be placed under a reorganized Drug Bureau administered by the public health agency. The Commission defined these [food safety] functions to include the regulations relating to adulteration of foods, standards of containers, tolerances of poisonous ingredients of foods and various milk requirements, that were regulated under the Federal Security Agency. All Federal Trade Commission responsibilities, for false advertising of foods and branding of wool and fibre products, would be transferred. The Commission recommended that the work of the Bureau of Internal Revenue in the Treasury that administered a tax on oleomargarine, renovated butter, and filled cheese be transferred to USDA. The Commission argued that too many agencies had jurisdiction over food and drug products, creating overlap and confusing the public. Four agencies exercised food regulatory functions, and some manufacturers had to comply with the regulations of more than one Federal agency. The recommendations of the Hoover Commission led to the creation of the Department of Health, Education, and Welfare in 1953. FDA was put under this new agency.

²⁵The Hoover Commission Report. U.S. Commission on Organization of the Executive Branch of the Government (1947-1949). Westport, Connecticut, Greenwood Press, 1970.

Dissenting Views

"A dissenting minority objected to splitting FDA because it would create rather than eliminate duplication and overlapping of services." Dissenters continued to say that splitting the functions would require two sets of laboratories and staffs working independently of each other and would limit the flexibility and economy of work assignments. Both the Committee on Medical Services and the Brookings Institution recommended that the [food safety] function be continued as part of a reorganized public health service within the Federal Security Agency or its successor.

Popular Name and Date

Restructuring of Meat and Poultry Products Inspection: Wholesome Meat Act of 1967, and the Poultry Products Act of 1968²⁶.

Description and Mission of Group Making Recommendations

Federal, State, and local meat inspections developed individually and separately. The Federal system was responsible for meats moving in interstate commerce and international trade. State and local authorities oversaw meats consumed in their own jurisdictions. Thus the control was mixed with some areas having rigid standards and others lax standards. From this background came a call for common standards and groups began promoting protective legislation.

The Talmadge-Aiken Act of 1962 provided for cooperation between Federal and State agencies in regulating the marketing of agricultural products. Few States took advantage of the authority to enter into broad cooperative agreements with the U.S. Department of Agriculture. Under it the States were to establish "equal to" systems. In 1967, President Johnson urged amending the law to provide greater protection to consumers and Federal assistance to States in developing State inspection programs. Congress passed the Wholesome Meat Act on December 15, 1967, which revised substantially the 1906 Meat Act. On August 18, 1968 the Wholesome Poultry Act became law and extended to poultry inspection many aspects of the meat inspection act approved in 1967.

Summary of Recommendations and Impact

Both Acts required that States have meat and poultry inspection programs "at least equal in rigor to" federally-run programs (under APHIS), even though the State-inspected plants could still only market their products within the State. Under deadlines of December 1969 (meat) and August 1970 (poultry), States could receive Federal matching funds to bring their programs up to Federal safety and purity standards. One year extensions were to be granted under certain conditions. The Acts encouraged uniformity in the inspection systems and closed loopholes in various phases of the inspection program. Annual reports to Congress on operations and effectiveness of the inspection system were required.

²⁶U.S. Department of Agriculture. Economic Research Service. National Economy and History Branch. Agriculture and Rural History Branch. Unpublished chapters from forthcoming history of the Food Safety and Inspection Service. Also see Wiser, Vivian. Part V: Meat and Poultry Inspection in the United States Department of Agriculture. In Wiser, Vivian, Larry Mark, H. Graham Purchase, 100 Years of Animal Health. 1884-1984. Beltsville, MD, The Associates of the National Agricultural Library, 1987.

Certain food additives were becoming a safety problem. The presence of nitrosamine, a carcinogen, in bacon was of concern. Food processors added nitrite as a curing agent to pork, and this addition caused the formation of nitrosamine when the naturally occurring amine and nitrite combined. Also Canada forbade meats from DES-treated animals (Diethylstilbestrol-a synthetic estrogenic drug) to enter its market and FDA considered banning its use altogether.

Dissenting Views

One State commissioner of agriculture felt that an ulterior motive was the complete federalization of meat inspection. There were charges that USDA was trying to extend its authority. A number of packing and processing representatives joined others from some State departments in opposition. Increasingly, the States dropped out of the meat inspection business because of its high cost. By 1976, APHIS inspectors monitored meat and poultry processing in 60% of the Nation's plants.

FOOD SAFETY UNDER THE FOOD AND DRUG ADMINISTRATION

Popular Name and Date

HEW Reorganization Order of March 1968.²⁷

Description and Mission of Group Making Recommendations

Department of Health, Education, and Welfare (DHEW) Reorganization Order of March 1968. President Lyndon Johnson pressed his cabinet and they initiated internal and external changes in FDA. The Bureau of Regulatory Compliance and the Bureau of Voluntary Compliance were consolidated into the Bureau of Compliance. Ten regional food and drug directorships were established to conform with the regional structure of DHEW. Plus the position of FDA was upgraded within the Public Health Service.

Summary of Recommendations and Impact

The Order placed FDA under the Public Health Service and in July 1968 made FDA a part of the newly created Consumer Protection and Environmental Health Service (CPEHS). FDA received resources devoted to pesticides, shellfish, product safety, and poison control from other Public Health agencies. FDA now began to operate under the Public Health Service Act.

Dissenting Views

CPEHS was the umbrella agency formed to deal with environmental problems but never received congressional authorization or appropriations. Other operating programs contributed funding and positions. Dr. Winton Rankin, Deputy Commissioner of FDA reportedly commented: "We gave him [C.C. Johnson, Director of CPEHS] whatever bit of lip service we had to but didn't offer much cooperation. He finally went under." Dr. Rankin also said that he thought that if CPEHS succeeded, FDA would cease to exist.²⁸

²⁷Brannon, Organizing and Reorganizing FDA. p. 135-174.

²⁸Brannon, Organizing and Reorganizing FDA. p. 135-174.

*Popular Name and Date***The Malek Report, December 10, 1969.²⁹***Description and Mission of Group Making Recommendations*

Analysis and Recommendations: The Food and Drug Administration Organizational Review, Frederick V. Malek, Deputy Undersecretary, Department of Health, Education, and Welfare, December 10, 1969. The committee was chaired by Mr. Malek and took 9 months to make its recommendations. Special Task Force on Reorganization of the Consumer Protection Programs, August 25, 1970. The report made an organizational and management study of the FDA. The recommendations were made to Dr. Charles C. Edwards, FDA Commissioner.

Summary of Recommendations and Impact

Proposed a reorganization of FDA because of a growing concern over FDA's ability to carry out its consumer protection responsibilities. The report recommended that a new Consumer Protection and Environmental Health Service be created separate from FDA with FDA becoming a major health agency reporting to the Assistant Secretary for Health and Scientific Affairs. A new Bureau of Foods, Pesticides, and Product Safety and a Bureau of Drugs would be created each with full responsibility and authority for all activities from initial research to final regulatory action. The rationale was that the new Food Bureau could concentrate on its major product areas without jeopardizing other product areas and would create clearer lines of authority for FDA's compliance activities. FDA Commissioner, Dr. Edwards claimed, "I am happy to say at this point in time [December 8, 1971] that all of the recommendations of the Malek committee in terms of the organization and management of FDA have been implemented."

Dissenting Views

Not Available

²⁹U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Commerce and Finance. Consumer Product Safety Act. Hearings, 92nd Congress, 2nd sess. Part 3. Nov. 1, 1971-Feb. 3, 1972. Serial No. 92-61. Washington, U.S. Govt. Print. Off., 1972.

*Popular Name and Date***The Ash Council Report of January 1971.³⁰***Description and Mission of Group Making Recommendations*

January 1971, President's Advisory Council on Executive Reorganization. Establishment of a Department of Natural Resources Organization for Social and Economic Programs.

Summary of Recommendations and Impact

The Council proposed that FDA be made part of a new Department of Human Resources whose purpose would be to assist in the development and well-being of U.S. citizens and "reform outdated social and economic policies embedded in the regulatory fabric of government." The justification was that independent regulatory commissions limited the effectiveness of the Federal government from responding to economic, technological, structural, and social change.

Dissenting Views

Several bills introduced during the 92nd Congress would have only partially accepted the Ash Council recommendations. For example, S. 1432 was introduced by Senator Percy. According to its sponsors, it would have promoted more effective management of the executive branch by reorganizing and consolidating certain related functions of the government in a new Department of Human Resources and for other purposes. S. 1432 did not include FDA. Congress appeared to be concerned about the concentration of responsibility in a single individual to head up new executive branch department with little congressional oversight.

³⁰President's Advisory Council on Executive Organization. Memoranda for the President of the United States. Establishment of a Department of Natural Resources Organization for Social and Economic Programs. Washington, D.C., U.S. Govt. Print Off., Feb. 5, 1971. p. 94. Percy, Charles. Remarks in the Senate. Congressional Record. v. 117, Apr. 1, 1971. p. 9089-9093.

Popular Name and Date

Senate Governmental Affairs Report on Federal Regulations, 1977.³¹

Description and Mission of Group Making Recommendations

U.S. Senate Committee on Governmental Affairs, Study on Federal Regulation. The Chairman of the Senate Committee on Governmental Affairs, Abraham Ribicoff, submitted this report to Walter F. Mondale, President of the Senate on December 21, 1977. The report was prepared under the authority of the Senate Resolution 71 that authorized the Governmental Affairs Committee to conduct a study on various aspects of the Federal regulatory process.

Summary of Recommendations and Impact

Senator Ribicoff hoped that the report would provide a basis for congressional action. The report recommended a transfer of USDA food regulatory functions to FDA. The report stated, "Divided responsibility for regulating food production has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniable costly, and unduly complex." The report asserted an urgent need to combine and rationalize the dual food regulation system that had existed over 70 years. "We believe the bifurcated food regulatory system should be unified in a single agency."

Dissenting Views

The proposal would have split the field force between the two administrations. USDA officials claimed that USDA's greatest strength was its network of field offices in operation throughout the country, as well as the experience and skills of its field staff. Transferring USDA employees to another agency would have weakened this network system.

³¹U.S. Congress. Senate. Committee on Governmental Affairs. Study on Federal Regulation. Senate Document no. 95-91, 95th Cong., 2d sess. v. V. Regulatory Organization. Dec. 1977. p. 140. Also mentioned in Hutt and Merrill, p. 18.

Popular Name and Date

President Carter's 1978 Government Reorganization Project or White House Study (never released).³²

Description and Mission of Group Making Recommendations

During testimony before Mr. Whitten's Subcommittee at various times, spokespeople for the Carter Administration referred to the President's White House Study for Reorganization. Two of the most prominent were Secretary of Agriculture, Bob Bergland, and Dr. Angelotti, Administrator of the Food Safety and Quality Service (FSQS) (a precursor of FSIS).

Summary of Recommendations and Impact

The project recommended consolidation of all food regulatory functions of FDA. Although the HEW Secretary Joseph Califano suggested that FDA take over USDA's meat and poultry inspection and labeling duties, the final report did not resolve where the new organization would be located. In 1977, USDA had formed the FSQS. Its mission was to enhance coordination among food inspection activities as well as food grading, certification and purchasing. USDA made very clear that it had reorganized itself along functional lines and therefore it did not believe consolidation with FDA would be beneficial.

Dissenting Views

USDA Secretary Bergland countered with the idea that FDA food inspection authority be transferred to the new FSQS, created in 1977. Secretary Bergland stated, "The President's Reorganization Task Force is reviewing the desirability of combining FDA food activities, and USDA food safety and quality activities operations. In November 1977, HEW proposed to consolidate USDA's meat and poultry inspection activities and the women-infants-children program with certain activities currently under HEW. In February, the Department proposed an alternative arrangement of functions. A decision will have to be made as to whether the activities should be combined---and if so---in which Department they should be located.

³²U.S. Congress. House Committee on Appropriations. Subcommittee on Agriculture, Rural Development, and Related Agencies. Agriculture, Rural Development and Related Agencies Appropriations for 1979. Hearings, Parts 1 and 4, Feb. 1978. Washington, U.S. Govt. Print. Off., 1978. p. 75 (pt.1), p. 367-371 (pt. 4).

Popular Name and Date

Dr. Lester Crawford, 1980.³³

Description and Mission of Group Making Recommendations

Dr. Lester Crawford was the newly appointed Food Safety and Inspection Service Administrator in 1980. In a speech at the 1980 U.S. Animal Health Association annual meeting, he recommended that one agency would do a better job in formulating food regulatory policies.

Summary of Recommendations and Impact

Dr. Crawford stated, "Managerially unsound and duplicative systems of regulation will cause us all to still be spinning on our collective wheels decades from now." He suggested a number of alternatives: 1) consolidation of all food safety functions within HHS; 2) transfer of FDA's Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA; or 3) at least merge CFSAN with CVM.

Dissenting Views

Several food safety activists objected to moving all food safety responsibility to USDA because USDA was not linked to the Public Health Service as FDA is. They argued that communication could be eased on food safety standards if all agencies were affiliated with public health agencies such as the Centers for Disease Control and the National Institutes of Health.

³³Crawford, Dr. Lester. Critique of Animal Health Regulation. Proceedings of the 84th Annual Meeting. Washington, D.C., U.S. Animal Health Association, 1980.

Popular Name and Date

Dr. Sanford Miller, 1989.³⁴

Description and Mission of Group Making Recommendations

Dr. Sanford Miller was the director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration from 1978 to 1987. He is a national voice on public policy relating to nutrition and food sciences.

Summary of Recommendations and Impact

In discussing the underlying philosophical dynamic for the leading food safety agencies which he believes has led to unnecessary controversies, Dr. Miller recommended that it was time to review the structure of food regulation in the United States. He suggested that it would be reasonable for the President and Congress to appoint a very senior level commission to review the requirements for an optimal food regulatory process and make recommendations. Dr. Miller stated, "The commission might very well conclude that the current setup is the best that we can devise, or it may propose a single agency, perhaps at the level of EPA."

Dissenting Views

Not Available

³⁴Miller, Dr. Sanford. *Quest for Safe Food: Knowledge and Wisdom*. 1989 S. B. Hendricks Memorial Lecture presented by Dr. Sanford A. Miller before the American Chemical Society, Miami Beach, Florida. September 11, 1989. U.S. Department of Agriculture. Agricultural Research Service. Washington, U.S. Govt. Print. Off., 1990. p. 11.

*Popular Name and Date***The Edwards FDA Advisory Committee, May 1991.³⁶***Description and Mission of Group Making Recommendations*

Final Report of the Advisory Committee on the Food and Drug Administration. The committee was chaired by Dr. Charles C. Edwards, the former FDA Commissioner (1969-1973), and former Assistant Secretary for Health (1973-75). One of its members became the FDA Commissioner, David A. Kessler. The purpose of the committee was to examine FDA's mission, responsibility, and structure according to its legislative mandate, and recommend how FDA could be strengthened to fulfill its mission. The committee was to provide advice accordingly to the Secretary of Health and Human Services and to the Assistant Secretary for Health.

Summary of Recommendations and Impact

The Committee recommended that FDA be removed from the Public Health Service (PHS) and that the FDA Commissioner report directly to the Secretary of Health and Human Services. It also recommended that the Secretary of HHS should redelegate to the Commissioner authority to issue regulations implementing all the laws that FDA administers and to manage the daily operations of the Agency.

The Food Policy Subcommittee of the Advisory Committee recommended that FDA move immediately to improve Center for Food Safety and Applied Nutrition (CFSAN) management system, increase its resources, upgrade the development of its program planning, and delegate additional authority to the CFSAN director. It also recommended that the Commissioner establish a task force to ensure FDA meet its nutrition labeling obligations and another to assist CFSAN in resolving scientific and technical issues. It also said that it found no evidence to show that FDA's performance would improve if its human food responsibilities were combined with those of USDA. It recommended the establishment of a consistent approach to risk assessment among regulatory agencies responsible for food safety (FDA, EPA, and USDA), including in food derived from animals.

Dissenting Views

The Secretary of HHS responded that the location in PHS was not the source of FDA problems. He contended that FDA has lots to gain from the close scientific interaction with other PHS agencies on issues such as AIDS epidemiology and research, pertussis vaccine, outbreaks of salmonella enteritidis,

³⁶U.S. Dept. of Health and Human Services. Advisory Committee on the Food and Drug Administration. Final Report. Charles C. Edwards, Chairman. May 1991. Washington, 1991. p. iii-iv, 19-24.

CRS-32

dental amalgam, and blood safety issues. According to this view, FDA interaction with other PHS agencies with a common mission leads to cooperation and interaction.

*Popular Name and Date***National Performance Review, September 1993.³⁶***Description and Mission of Group Making Recommendations*

Vice President Al Gore published his report of the National Performance Review on September 7, 1993. He had been asked by President Clinton to undertake a 6-month study of the Federal bureaucracy and make recommendations on how to create a government that works better and costs less.

Summary of Recommendations and Impact

The Review recommends eliminating the FSIS of USDA as a separate agency by consolidating all food safety responsibilities under the FDA.

Dissenting Views

A food safety panel advising the Review staff reportedly had recommended an independent agency which would administer a science-based system that applies the same standards to all foods and could prevent foodborne illnesses. The independent agency would conduct research and eliminate illogical and inconsistent treatment of food products posing similar risk. This view was not accepted in the final National Performance Review report. Some in Congress would prefer that FSIS absorb food and seafood inspection responsibilities because FSIS has a substantial network around the country, and it has shown that it can communicate with the public health service when necessary. For example, House Speaker Thomas S. Foley has said that, if USDA regulated all foods, the FDA would be free to concentrate on the safety of drugs.³⁷

³⁶Gore, Al. From Red Tape to Results: Creating a Government That Works Better and Costs Less. Report of the National Performance Review. Washington, Sept. 7, 1993. p. 101. Cooper, Kenneth J. Hill Turf Fights May 'Reinvent' Gore Proposals. Washington Post. Sept. 13, 1993, p. A19. Rodney E. Leonard. A Single Food Safety Agency. Nutrition Week. v. 23, Sept. 10, 1993. p. 2.

³⁷Cooper, Kenneth J., Hill Turf Fights May 'Reinvent' Gore Proposals. Washington Post, Sept. 13, 1993, p. A19. Rodney E. Leonard. A Single Food Safety Agency. Nutrition Week. v. 23, Sept. 10, 1993, p. 2.

TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1993.

NAME AND SOURCE	PROPOSED CHANGES IN ORGANIZATION
The Hoover Commission Report. U.S. Commission on Organization of the Executive Branch of the Government (1947-1949). Westport, Connecticut, Greenwood Press, 1970.	This report recommended that all regulatory functions relating to food products to protect the consumer be transferred to USDA and that those relating to other products be placed under a reorganized Drug Bureau administered by the public health agency.
Department of Health, Education, and Welfare Reorganization Order of March 1968. Found in: Brannon, Michael. Organizing and Reorganizing FDA. Seventy-Fifth Anniversary Commemorative Volume of Food and Drug Law. Food And Drug Law Institute Series. Washington, D.C. 1984. p. 135-174.	The Order placed FDA under the Public Health Service and in July 1968 made FDA a part of the newly created Consumer Protection and Environmental Health Service (CPEHS). FDA received resources devoted to pesticides, shellfish, product safety, and poison control from other Public Health agencies. FDA now began to operate under the Public Health Service Act.
Restructuring of Meat and Poultry Inspection: Wholesome Meat Act of 1967, and the Poultry Products Act of 1968. U.S. Department of Agriculture. Economic Research Service. National Economy and History Branch. Agriculture and Rural History Branch. Unpublished chapters from forthcoming history of the Food Safety and Inspection Service.	Both Acts required that States have meat and poultry inspections programs "at least equal in rigor to" federally-run programs (under APHIS), even though the State-inspected plants could still only market their products within the State. Under deadlines of December 1969 (meat) and August 1970 (poultry), States could receive Federal matching funds to bring their programs up to Federal safety and purity standards. One year extensions were to be granted under certain conditions.

(continued)

CRS-35

TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1993.

NAME AND SOURCE	PROPOSED CHANGES IN ORGANIZATION
White House Conference on Food, 1969. White House Conference on Food, Nutrition, and Health. Final Report. Washington, D.C. 1969.	The Conference recommended that there should be one Federal regulatory policy with respect to safety, sanitation, identity, and labeling of foods.
U.S. General Accounting Office. Need to Reassess Food Inspection Roles of Federal Organizations. Department of Agriculture, Department of Defense, Department of Health Education, and Welfare, Department of the Interior. Report to the Congress by the Comptroller General of the United States. Rept. No. B-168966. June 30, 1970. Although the report did not specifically recommend consolidation, it criticized the overlapping inspection activities among USDA, FDA, and other Federal Agencies. Instead it recommended that the Director, Bureau of the Budget, make a detailed evaluation of the Federal food inspection system to see how to improve its administration and determine if it is feasible to consolidate some of the inspections.	Although the report did not specifically recommend consolidation, it criticized the overlapping inspection activities among USDA, FDA, and other Federal Agencies. Instead it recommended that the Director, Bureau of the Budget, make a detailed evaluation of the Federal food inspection system to see how to improve its administration and determine if it is feasible to consolidate some of the inspections.
1969 Malek Report. U.S. Congress. House. Committee on Interstate and Foreign Commerce. Subcommittee on Commerce and Finance. Consumer Product Safety Act. Hearings, 92nd Congress, 2nd sess. Part 3, Nov. 1, 1971-Feb. 3, 1972. Serial No. 92-61. Washington, U.S. Govt. Print. Off., 1972.	The report recommended that a new Consumer Protection and Environmental Health Service be created separate from FDA with FDA becoming a major health agency reporting to the Assistance Sec. for Health and Scientific Affairs. A new Bureau of Foods, Pesticides, and Product Safety and a Bureau of Drugs would be created each with full responsibility and authority for all activities from initial research to final regulatory action.

(continued)

TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1983.

NAME AND SOURCE	PROPOSED CHANGES IN ORGANIZATION
<p>The Ash Council Report. President's Advisory Council on Executive Organization. Memoranda for the President of the United States. Establishment of a Department of Natural Resources Organization for Social and Economic Programs. Washington, D.C.: U.S. govt. Print Off., February 5, 1971. p. 94. Percy, Charles. Remarks in the Senate. Congressional Record. v. 117, April 1, 1971. p. 9089-9093.</p>	<p>This report proposed that FDA be made part of a new Department of Human Resources whose purpose would be to assist in the development and well-being of U.S. citizens and "reform outdated social and economic policies embedded in the regulatory fabric of government." The justification was that independent regulatory commissions limited the effectiveness of the Federal Government from responding to economic, technological, structural, and social change.</p>
<p>1972 Hearings before the U.S. Senate on S. 3419. U.S. Congress. Senate. Report of the Senate Commerce Committee. S. Rpt. 92-749; Senate Government Operations Committee. Hearings. Senate Labor and Public Welfare Committee. Hearing. S. Rpt. 92-835.</p>	<p>The Consumer Safety Act of 1972 (S. 3419) provided for the transfer of HEW functions administered through FDA, such as food and drugs, and the Division of Biologics Standards (DBS) and other product safety functions of the Department of Commerce and the Federal Trade Commission to the independent Consumer Safety Agency to be created by S. 3419. The purpose was to protect consumers against unreasonable risk of injury from hazardous products. The independent agency would have responsibility to set product safety standards for all consumer products representing unreasonable risk of injury or death. S. 3419, became the umbrella legislation and was called the Food, Drug, and Consumer Product Safety Act of 1972. It passed the Senate on June 21, 1972.</p>
<p>1972 Ralph Nader Report. Wellford, Harrison. Sowing the Wind: A Report from Ralph Nader's Center for Study of Responsive Law on Food Safety and the Chemical Harvest. New York: Grossman Publishers, 1972. p. 354;</p>	<p>This report found that food inspection "remains embarrassed by departmental conflicts of interest and overlapping jurisdictions in USDA and FDA." In its conclusions, the report recommends that meat inspection and chemical monitoring in USDA and the food inspection functions of FDA, should be transferred to a new food safety agency where the goal of protecting public health would be consolidated.</p>
<p>1977, Senate Committee on Governmental Affairs Report. U.S. Congress. Senate. Committee on Governmental Affairs. Study on Federal Regulation. Senate Document No. 95-91, 95th Cong., 2d sess. vol. V. Regulatory Organization. December 1977. p. 140.</p>	<p>It recommended a transfer of USDA food regulatory functions to FDA.</p>

(continued)

TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1993.

NAME AND SOURCE	PROPOSED CHANGES IN ORGANIZATION
President Carter's 1978 Government Reorganization Project or White House Study (never released). U.S. Congress. House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, and Related Agencies. Agriculture, Rural Development and Related Agencies Appropriations for 1978. Hearings, Parts 1 and 4, Feb. 1978. Washington, D.C., U.S. Govt. Print. Off., 1978. p. 75 (pt.1), p. 367-371 (pt. 4).	It recommended consolidation of all food regulatory functions of FDA.
Dr. Lester Crawford Speech. Crawford, Dr. Lester. Critique of Animal Health Regulation. Proceedings of the 84th Annual Meeting. Washington, D.C., U.S. Animal Health Association, 1980.	Dr. Crawford suggested: 1) consolidation of all food safety functions within HHS; 2) transfer of FDA's divisions of Center of Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) to USDA; or 3) at least merge CFSAN with CVM.
September 1989. Dr. Sanford Miller. Quest for Safe Food: Knowledge and Wisdom. 1989 S. B. Hendricks Memorial Lecture presented by Dr. Sanford A. Miller before the American Chemical Society, Miami Beach, Florida. September 11, 1989. U.S. Department of Agriculture. Agricultural Research Service. Washington, D.C., U.S. Govt. Print. Off., 1990. p. 11.	He recommended that a special commission be set up to make recommendations on the optimal food safety regulatory process which may be a single agency.
May 1991, The Edwards Committee Report. U.S. Dept. of Health and Human Services. Advisory Committee on the Food and Drug Administration. Final Report. Charles C. Edwards, Chairman. May 1991. Washington, D.C., 1991. p. iii-iv, 19-24.	It recommended that FDA be removed from the Public Health Service (PHS) and the FDA Commissioner report directly to the Secretary of Health and Human Services
June 1992 Risk-based Food Safety Inspection. U.S. General Accounting Office. Food Safety and Quality: Uniform, Risk-based Inspection system Needed to Ensure Safe Food Supply. GAO/RCED-92-152, June 1992.	It recommended that Congress hold oversight hearings to evaluate options for revamping the Federal food safety and quality system including creating a single food safety agency responsible for administering a uniform set of food safety laws.
August 3, 1993, Senator Durenberger introduced S. 1349, Food Safety and Inspection Agency Act of 1993. It was referred to the Senate Committee on Governmental Affairs.	The act, if passed, would center all food safety and inspection activities in a single, independent agency which would, with the guidance of a 15 person expert commission, set uniform risk-based inspection standards by which food safety would be ensured. It would also establish a State-Federal communications network to educate consumers on potential microbial diseases.

(continued)

CRS-38

TABLE 1. Chronological List of Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1955-1993.

NAME AND SOURCE	PROPOSED CHANGES IN ORGANIZATION
<p>August 17, 1993. Carol Tucker Foreman, Safe Food Coalition. Reinventing Meat and Poultry Inspection: Building a Public Health Based Program.</p> <p>August 17, 1993. These recommendations reflect support from the Am. Public Health Association; Ctr. for Science in the Pub. Interest; Consumer Federation of Am.; Consumers Union; Food and Allied Service Trades, AFL-CIO; Govt. Accountability Proj.; Nat. Consumers League; Pub.Citizen; Pub. Voices for Food and Health. Pol. United Food and Comm. Workers Intern. Union.</p>	<p>It supports the June 1992 GAO proposal to combine food safety functions and recommends that it be adopted because there appeared to be no justification for meat and poultry inspection to be separated from the rest of food inspection. It also recommends that the Clinton Administration combine all food safety programs within HHS and elevate FDA to a level equal to the Social Security Administration or combine all food inspection in a new agency. Such an agency could combine the functions of FDA and USDA and the pesticide programs of EPA with the existing programs of the Consumer Product Safety Commission and rename and reconfigure that agency. It would bring together programs and personnel with similar goals and may offer an opportunity to reduce administration and personnel costs.</p>
<p>September 7, 1993. National Performance Review. Gore, Al. From Red Tape to Results: Creating a Government that Works Better and Costs Less. Report of the National Performance Review. Washington, D.C. Sept. 7, 1993. p. 101.</p>	<p>It recommends eliminating the FSIS as a separate agency by consolidating all food safety responsibilities under the FDA.</p>



United States
Department of
Agriculture

Office of Inspector General

Audit Report

FOOD SAFETY AND INSPECTION SERVICE
EVALUATION OF
REGULATION OF CORNHUSKER PACKING COMPANY
OMAHA, NEBRASKA
REPORT NO. 24800-1-KC

AUGUST 1993

NOTICE - THIS REPORT RESTRICTED TO OFFICIAL USE

This evaluation is provided to program officials solely for their review and comments on the subjects reported. Recipients of this report are not authorized to make any further distribution or release of this information except for official review and comments.

UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL - AUDIT
GREAT PLAINS REGION
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KANSAS CITY, MISSOURI 64141



United States
Department of
Agriculture

Office of
Inspector
General

Washington,
D.C.
20250

DATE: August 12, 1993

REPLY TO
ATTN OF: 24800-1-KC

SUBJECT: Evaluation - Regulation of Cornhusker Packing Company,
Omaha, Nebraska

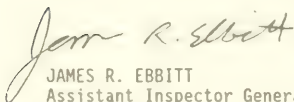
TO: H. Russell Cross
Administrator
Food Safety and Inspection Service

We have completed an evaluation of Food Safety and Inspection Service's regulation of the subject slaughter plant. Besides conducting work at the above plant, we also conducted reviews of appropriate records at the regional and area offices. In addition, we interviewed numerous inspectors who worked at the plant as well as appropriate regional and area office management officials. We also visited several other slaughter plants in the circuit where this plant was located. Attached are the results of our review and recommended corrective actions.

Your written response, dated August 3, 1993, is attached as exhibit C. Although your response expressed general concurrence to the recommendations, we need additional information before any management decisions can be reached.

In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the specific corrective action taken or planned and the timeframes for implementation for each of the recommendations. Please note that the regulation requires a management decision to be reached on all findings and recommendations within a maximum of 6 months from report issuance.

We appreciated the assistance you and your staff provided to us in our review.



JAMES R. EBBITT
Assistant Inspector General
for Audit

EXECUTIVE SUMMARY

EVALUATION OF FOOD SAFETY AND INSPECTION SERVICE REGULATION OF CORNHUSKER PACKING COMPANY

PURPOSE

On May 20, 1993, the Secretary announced that the Department had stopped the operations of Cornhusker Packing Company, a meat slaughter plant in Omaha, Nebraska. Earlier in the week, a televised newscast showed several scenes of unsanitary conditions occurring at the federally inspected plant. The plant was temporarily closed for failing to meet U.S. Department of Agriculture (USDA) standards and was not allowed to resume slaughter operations until the afternoon of May 25. The Secretary requested that we review the plant to determine why it was failing to meet these standards and why USDA had not insisted on corrective action earlier. Our objective was to determine if Food Safety and Inspection Service (FSIS) officials had taken timely and effective corrective actions to ensure the plant followed meat inspection regulations.

RESULTS IN BRIEF

Plant management officials had not corrected the sanitation deficiencies that have been ongoing at Cornhusker Packing Company for many years. The plant had a long history of rodent infestation, poor maintenance, and unsanitary practices. During our site review starting June 8, 1993, we found that FSIS inspection personnel allowed the plant to operate when conditions similar to the conditions depicted on the televised newscast still were occurring. Specifically, we found the following.

- Meat products were contaminated with feces and other unidentifiable particles and, while contaminated, came in contact with other edible organs.
- Oversized carcasses were touching contaminated surfaces, including the kill floor, and water was splashing from the kill floor onto hanging carcasses.
- Carcasses in coolers and product ready for packing had unidentifiable particles on their surfaces.

- Plant facilities were old and not properly maintained, allowing contamination and access by pests.

These conditions were allowed to persist because of poor supervision over the FSIS inspection process at the plant. The FSIS regional office, the area office, the circuit supervisor, and the inspector-in-charge at the plant all failed to adequately supervise the in-plant inspection staff. There were inadequate supervisory reviews of the performances of lower level employees, no independent reviews of the plant, no rotations of the inspector-in-charge, and finally, ineffective communication between the circuit supervisor and higher levels of management. Conditions identified by inspectors were not properly followed to resolution by FSIS management, which generally failed to recognize the problems at the plant. We did not, however, confirm any specific instances in which FSIS failed to back up a decision by inspectors, as was alleged during the newscast.

KEY RECOMMENDATIONS

We recommended that FSIS take immediate action to ensure the wholesomeness of the product at Cornhusker, and institute controls to ensure that agency management stays informed of problem plants and finds solutions for chronic deficiencies. Such controls would take the form of greater communication within the inspection chain of command, as well as official policy that would, among other things, result in plants initiating their own quality control activities instead of waiting for FSIS to require correction.

AGENCY POSITION

On June 18, 1993, FSIS elevated Cornhusker Packing Company to Stage II of a Progressive Enforcement Action, an administrative sanction that requires the plant to correct its cited deficiencies according to a schedule set by FSIS. FSIS' corrective action plan covers inspection and plant operations. We believe that although some of the requirements of the corrective action plan were vague, it should bring Cornhusker up to USDA standards. As of July 22, FSIS officials reported the plant was making the corrections required by the plan.

FSIS expressed general concurrence with our recommendations in the written response, dated August 3, 1993. The response showed that FSIS plans to move quickly and decisively to ensure management practices do not permit repetitions of inadequate responses to plant compliance problems. The response also showed that our recommendations can be incorporated into improvements that FSIS has set in motion for pathogen reduction, program review, and stronger supervision and oversight of the plant inspection processes.

INTRODUCTION

BACKGROUND

Cornhusker Packing Company (Cornhusker) has been in operation in Omaha, Nebraska, since 1950. It is a small family-run company, slaughtering from 100 to 700 cattle per day for human consumption. Inspection at the plant is provided by five Food Safety and Inspection Service (FSIS) inspectors as well as an inspector-in-charge (supervisory inspector) and a veterinary medical officer. The plant generally buys cows and bulls, which means that it slaughters older animals such as cull dairy cows that are not usable, for more expensive cuts of meat such as steaks, but are butchered primarily for sale to meat processing plants to be processed into ground beef. Because the cattle are older, they are more apt to have diseases and therefore present a greater risk to consumers. Such animals require more inspection effort than healthy steers and heifers that are slaughtered.

The Federal Meat Inspection Act requires that each animal slaughtered in a Federal or a State establishment be examined before, during, and after slaughter. These ante- and postmortem inspections are conducted by veterinarians or by trained inspectors working under their supervision.

The general purpose of antemortem inspections is to determine whether each animal present for slaughter is normal or abnormal. Those designated as normal are sent directly to be killed; those found to be abnormal are categorized as unfit for slaughter, or acceptable for slaughter but having a condition that might influence carcass disposition upon postmortem examination. The main purpose of postmortem examinations is to detect disease and other abnormal conditions that require condemnation.

FSIS inspectors are also responsible for inspecting the sanitation of the facility. This includes structural aspects of the premises, water supply, manure and sewage disposal, equipment, personnel and other health-related features of the plant environment. When sanitation problems are found, the inspector attaches a "reject tag" to the unacceptable item, warning that it must not be placed in service until it has been brought up to standard. The inspector also completes a daily sanitation report that covers such items as plant cleanliness and rodent-insect control.

Once a violation is identified, it must be corrected to the inspector's satisfaction before operations may continue.

Cornhusker has had a history of sanitation violations, especially in the areas of rodent control and plant cleanliness. FSIS inspectors have long noted rodent infestation as a recurring problem at the facility, and they have documented continuing deterioration of the kill floor. Generally, plant management has not cooperated with FSIS efforts and has even been antagonistic towards the FSIS presence in the plant. We observed the plant manager discussing an inspection decision with the inspector-in-charge in a loud, vulgar, and confrontational manner. FSIS inspectors in the plant have felt frustrated in their efforts to get the company to respond to their concerns and have pressed FSIS management for more decisive action. In February 1993, an anonymous memo to FSIS headquarters management alleged that the plant was unsanitary and that an FSIS employee had acted improperly. Shortly after the area supervisor reviewed the rodent problem at the plant, a second memo appeared, critical of the area supervisor's review. Within a month, the news media aired its report detailing sanitation violations that were not corrected by FSIS management.

OBJECTIVES

Our objectives were to determine if FSIS ensured the plant met Federal meat inspection requirements and if FSIS management was adequate to obtain corrective action on adverse conditions, including conditions reported through the media.

SCOPE

We performed an evaluation of FSIS inspection operations at Cornhusker Packing Company, Omaha, Nebraska. We reviewed inspection records for the period January 1, 1991, through June 10, 1993. With the assistance of a technical expert provided by the FSIS Program Review Division, Lawrence, Kansas, we performed an indepth review of plant operations from June 8 through June 11, 1993. We also visited five additional slaughter plants in Omaha, Nebraska, to determine if conditions similar to those found at Cornhusker existed in those plants. We interviewed the plant manager and his attorney, current and previous inspectors and inspectors-in-charge assigned to Cornhusker, circuit, area, regional, and national office personnel. In addition, we interviewed and obtained records from officials of the FSIS Compliance Division and of the Packers and Stockyards Administration.

I. FSIS ALLOWED NUMEROUS PLANT DEFICIENCIES TO OCCUR WITHOUT ADEQUATE CORRECTIVE ACTION

Many of the deficiencies reported in the newscast and found during prior FSIS reviews and our onsite review were of a long-term nature. They resulted from ineffective FSIS supervision and from uncooperative plant managers who engaged in short-term corrective actions while operations at the plant steadily deteriorated. In some instances when the inspection staff reported unsanitary conditions and adulterated meat, the FSIS circuit supervisor, area office, and regional office did not require the plant to ensure that improper slaughter procedures would not recur. The area and regional office officials attributed their supervisory difficulties to revisions in work duties for the circuit supervisor, inadequate communication throughout the inspection chain of command, and special assignments which diverted the attention of the area and regional office staff. Nevertheless, FSIS managers did not classify Cornhusker as a problem plant or select it for special reviews. No special reviews were conducted at Cornhusker, and the deficient conditions were not identified to higher levels of management.

During our onsite review, we identified unsanitary practices still occurring at Cornhusker, including conditions similar to those depicted on the televised newscast (see exhibits A and B). Also, we found the plant had a long history of deficiencies that had been noted in Daily Sanitation Reports, Process Deficiency Records, Plant Improvement Plans, and correspondence. Some of these deficiencies became pronounced in recent years, as the following summary shows:

Condition (1/82 through 6/10/93)	Number of Occurrences
Unsanitary Practices	45
Rodent Problems	52
Contamination of Product	47
Damaged Floors, Walls, and Ceiling	9
Carcasses Dragged on Floor	3

The number and type of deficiencies listed in the exhibits indicate that plant facilities had been deteriorating for a long time and that both plant managers and inspectors were unable to bring operations to a satisfactory level, even after the newscast in May 1993. One example of Cornhusker's deterioration was the poor maintenance of its outside premises. The poor housekeeping that

Cornhusker practiced on the outside of its facility produced a ready-made refuge for flies, rats, and other vermin.

The plant manager and his attorney told us that they believed that the newscast unfairly presented conditions at the plant and that they had fully responded to all FSIS demands for correcting operating deficiencies. However, the plant manager and his attorney declined to discuss plant operational matters or evaluate FSIS inspection staff performance.

FSIS placed Cornhusker under a Progressive Enforcement Action on May 21, 1993. The causes cited for the action included improper rodent control; violations of carcass standards for fecal, ingesta, and milk contamination; and carcass contamination resulting from violations of basic cleanliness and sanitation standards. Effective June 18, 1993, FSIS elevated Cornhusker to Stage II of the Progressive Enforcement Action.

RECOMMENDATION NO. 1

Implement appropriate microbial contamination testing at Cornhusker.

II. FSIS MANAGEMENT OVERSIGHT INADEQUATE TO ASCERTAIN EXTENT OF PLANT'S PROBLEMS

The problems with sanitation and with inadequate corrective action continued at Cornhusker because of poor supervision over the FSIS inspection process. Under FSIS' supervision, plant management officials did not perform their responsibilities to maintain equipment and facilities in a sanitary manner and produce a wholesome, unadulterated product. The regional office, the area office, the circuit supervisor and the inspector-in-charge all failed to adequately supervise the in-plant inspection staff. There were no independent reviews of the plant since 1990 and no documentation to show that the circuit supervisor was sufficiently familiar with plant problems to identify that the inspector-in-charge was not achieving adequate corrective actions. Also, there was ineffective communication between the levels of the FSIS chain of command. FSIS had several indications, including two complaint memos from FSIS employees, that the plant was not being operated properly, but these concerns were not regarded with the same seriousness by FSIS management as they were by the in-plant FSIS staff.

FSIS MANAGEMENT WAS NOT AWARE OF PLANT'S HISTORY

The area office was not aware of the history of Cornhusker because of a breakdown in communication between the circuit supervisor and the area supervisor. The area supervisor did not monitor FSIS activity at the plant, and the circuit supervisor himself did not provide sufficient supervision to the

inspector-in-charge to identify problems at the plant and obtain corrective action on them.

At one time circuit supervisors were required to periodically conduct indepth reviews of each of their plants, but these reviews were discontinued to allow the circuit supervisor more time for actual supervision. According to the area supervisor, in October 1992, he became concerned that he was not being informed of potential problems in a timely manner, and he reinstated the indepth reviews. All inspectors-in-charge within the area were instructed to perform an indepth review and reinspect one section of the plant each month. Circuit supervisors were encouraged to perform sections of the reviews and monitor the inspectors-in-charge to ensure the reviews were completed.

We reviewed the area office monitoring logs which were initiated in October 1992. These records showed that most circuit supervisors in this area had participated in one or more reviews in most plants in their circuit. However, the monitoring logs did not document

any reviews by the Omaha circuit supervisor, who had responsibility for Cornhusker.

The inspector-in-charge at Cornhusker had performed an indepth review of the plant in October 1992 (identifying 10 deficiencies, including crumbling floors) and performed 4 partial reviews after that date. He documented these reviews on FSIS Form 8110-2, Establishment Review and Assessment Worksheet. In conjunction with these reviews, the inspector-in-charge was completing plant improvement plans for long-term plant improvements and forms 8110-2A for items that could be quickly corrected. We found no evidence the circuit supervisor had reviewed these documents or performed his own reviews to determine the effectiveness of the inspector-in-charge's performance. Although the log showed that none of the reviews were done, the area office had not taken steps to require the circuit supervisor to do them.

The area supervisor noted that within the past few years, the area office stopped receiving quarterly reports from circuit supervisors. These reports described inspection trends in the circuits and recent developments in problem plants. (According to the regional director, he was unaware of any FSIS requirements for quarterly reports or any similar report.) The area supervisor believed that when the quarterly reports stopped, the area office did not become aware of potential problems as promptly as it had when the reports were still issued. The area supervisor said he was not aware of the adverse conditions at Cornhusker and concluded that lack of reporting by circuit supervisors resulted in a failure of communication.

The area supervisor said he visited Cornhusker once when he first assumed his position, and had been in the plant at least twice on specific complaints, such as employee grievances, which would not have involved a review of plant operations. He said he performed a special review for rodent infestation in March 1993. However, he stated he did not review the area office files for the plant when he performed the review. He also did not review the Process Deficiency Records or Sanitation Reports on file in the FSIS office in the plant. According to the area supervisor, he was not aware of documented rodent problems which occurred in 1990 and 1992. While he was aware that in January 1993 a rat had actually been seen on the kill floor, he was not aware of the history of rodent problems at the plant. He stated that if he had been fully aware of these circumstances, his conclusion in March 1993 may have been different. He said that although he had planned to return to the plant about 2 weeks after his visit in March, he did not return because of other priorities.

Program Review Division personnel told us that they currently direct their reviews to circuits and do not analyze circuit deficiencies to detect trends in area offices.

RECOMMENDATION NO. 2

Require the regional and area office personnel to become fully aware of problems and conditions in the plants in their various areas of responsibility and to concentrate management efforts on taking proactive corrective actions, rather than waiting to react to a problem plant where necessary corrective actions require administrative enforcement.

RECOMMENDATION NO. 3

Require the area office to develop adequate lines of communication with all circuit supervisors in the area.

RECOMMENDATION NO. 4

Require the Program Review Division to develop a method of analyzing trends of deficiencies in area offices.

**FSIS PERFORMANCE WEAKNESSES WERE
NOT DETECTED**

Besides the failure by FSIS to keep all levels in the chain of command informed of problem plants, FSIS managers were also not fully aware of weaknesses in the performances of their subordinates or did not take steps to strengthen them. Both the circuit supervisor and

area supervisor stated they were aware of problems with the inspector-in-charge's performance, even though the circuit supervisor gave the inspector-in-charge good job evaluations. On the other hand, the area supervisor was not familiar enough with the circuit supervisor's performance to detect problems and did not report any on his evaluation of that performance.

Inspector-in-Charge

The inspector-in-charge at the time of the newscast had been assigned to that position since late 1989. He worked onsite at the plant, and his responsibilities included taking corrective action when inspection violations were identified. As we have already mentioned, the plant had a long history of recurring sanitation deficiencies. The inspector-in-charge said that plant management was to blame. After plant managers were informed of problems, they would make short-term corrections, and then the problem would recur. He cited continued problems with crumbling floors as an

example of short-term corrective action and the absence of a preventive maintenance program.

One example where the inspector-in-charge did not force corrective action involved the presence of a rat on the kill floor. Although the incident could have allowed a shutdown of the plant until meaningful corrective action was taken, the inspector-in-charge only stopped production for 7 minutes while the floor was hosed down.

In response to our question of why corrective action had not been taken at the plant sooner, we were told that the inspector-in-charge may have concentrated on cattle inspections and largely ignored problems of plant sanitation and deterioration of facilities. The circuit supervisor believed that the inspector-in-charge had not been strong enough to stand up to plant management. The area supervisor concurred in this assessment. The circuit supervisor also said that he had wanted to reassign the inspector-in-charge because of his weak enforcement but was always overruled by the area supervisor. (We noted, however, that the inspector-in-charge was reassigned to another plant the week after the newscast.)

On June 1, 1993, shortly after the newscast, the circuit supervisor performed an indepth review of Cornhusker and documented approximately 100 deficiencies. When the inspector-in-charge reviewed 32 items at Cornhusker during his partial reviews on March 10 and May 6, 1993, he identified only 4 deficiencies. For these same 32 items, the circuit supervisor's review noted 16 deficiencies.

Circuit Supervisor

The circuit supervisor was assigned to the circuit in the early 1970's. His duties included (1) establishing and maintaining inspection standards and managing and evaluating personnel, (2) preparing for onsite plant visits by reviewing the performance histories of inspectors-in-charge and in-plant performance systems, and (3) determining which inspection activities were to be stressed, including sanitation and plant and equipment improvements.

Unlike the inspector-in-charge, the circuit supervisor was not assigned to any one location, but moved routinely among the 11 plants located in his circuit. He estimated he visited the Cornhusker plant at least once every month. However, as we mentioned in connection with management's unawareness of plant history, there was no evidence the circuit supervisor reviewed the inspection reports completed by the inspector-in-charge.

The area supervisor said that the Omaha Circuit Supervisor was a senior supervisor with an excellent reputation. He therefore placed great confidence in him to be fully aware of situations in his plants and to provide needed information to the area office.

He stated that in retrospect that confidence was misplaced. He believed that the circuit supervisor should at least have been counselling the inspector-in-charge to be more forceful in dealing with plant management.

The regional director said from his trip to Cornhusker on May 24, 1993, it was obvious that "bandaids" had been used to fix problems. He told plant management that part of their problem was that they did not take the initiative. For example, although the plant could have taken responsibility to clean all working areas before the start of operations, it sent a "bucket brigade" of plant employees to follow the inspector around and correct deficiencies he pointed out. The regional director said that if several things were found dirty, the inspector should have tagged the entire area until the plant took corrective action. According to the regional director, it was the circuit supervisor who should have been keeping the area office informed of problems with the plant, and he believed that possibly the circuit supervisor was complacent. (During our onsite review, the regional office assigned the circuit supervisor to a special detail away from the circuit.)

Higher Levels of Management

Personnel at the area, regional, and headquarters offices advised there were conditions at Cornhusker of which they were not aware. They attributed this to the ineffective communication between the circuit supervisor and area office and stated that had the area office been informed, corrective action would have been taken sooner.

RECOMMENDATION NO. 5

Require the area office to ensure that circuit supervisors monitor the performances of inspectors-in-charge through plant review.

RECOMMENDATION NO. 6

Conduct a survey of regional office and area office managers to determine the extent of techniques used to manage lower level units (areas and circuits) to ensure a satisfactory job performance.

RECOMMENDATION NO. 7

Conduct a survey of inspectors-in-charge within the Topeka area and determine the benefits of periodically rotating these inspectors among the plants in the area.

**CORNHUSKER WAS NOT INCLUDED IN
SPECIAL REVIEWS**

Several inspectors who had worked at Cornhusker expressed concern that the plant was not included in several special reviews initiated by the FSIS national office. We noted that two other Omaha plants were randomly selected by the FSIS headquarters for a special review performed during the summer of 1992. Initial visits noted several critical violations, and followup reviews showed substantial improvements. Our review of these plants and three other Omaha plants disclosed no conditions affecting product wholesomeness.

We were particularly concerned that Cornhusker was not included on a February 10, 1993, list of plants designated for special review. The plants on the list all engaged in "cattle kills," like Cornhusker, but area office personnel did not categorize Cornhusker as a problem plant.

In order to categorize a facility as a problem plant, the area office was to consider four categories: condition of plant equipment, cleanliness of practices, cleanliness of plant dressing procedures, and attitude of plant management. The assistant area supervisor said the only known concern about Cornhusker at the time of the special reviews was that it had a history of difficult management. The assistant area supervisor cited a Program Review Division report for Cornhusker performed in June 1990 which reported relatively minor problems. Based on that review, the assistant area supervisor believed the only category in which Cornhusker rated unsatisfactory was management's attitude. The area supervisor, on the other hand, told us he knew about plant sanitation problems at Cornhusker, and only recently became aware of the history of uncooperative management. From our review of area office dockets, sanitation reports, and process deficiency records, we concluded the plant should have been considered a problem plant in February 1993 and included in the special review performed in March 1993.

About the time plants were being selected for review, FSIS headquarters received a memo addressed to the Deputy Administrator, Inspection Operations, apparently from FSIS inspectors. This memo stated that Cornhusker was a filthy plant and asked for assistance in obtaining corrections. The complaint on sanitation was forwarded to the regional director and then to the area supervisor for review. FSIS headquarters later received another memo that the

visit to Cornhusker by the area supervisor did not result in a satisfactory resolution of the problems at Cornhusker.

We believe that a review by an independent person or team not directly responsible for Cornhusker could have resulted in earlier correction of the problems at Cornhusker.

RECOMMENDATION NO. 8

Establish controls, including independent reviews, to assess the validity and extent of employee complaints when allegations include charges supervisors are not responding to problems.

INADEQUATE ACTION ON ALLEGATION OF MISCONDUCT

FSIS headquarters officials did not promptly refer a complaint of improper conduct to OIG for investigation. On February 8, 1993, FSIS headquarters received an anonymous memo alleging improprieties on the part of an FSIS employee at Cornhusker. (This memo also included other complaints about the plant's operation.) In early March, the Deputy Administrator, Inspection Operations, reviewed the memo and forwarded it to the regional director, asking him to address the sanitation issues in the memo. According to an Inspection Operations official, they did not realize the gravity of the situation until the newscast on May 17. After the newscast, they contacted OIG and requested an investigation, which OIG has completed.

RECOMMENDATION NO. 9

Instruct all employees to promptly refer allegations of employee misconduct to the Office of Inspector General.

III. FSIS NEEDS TO DEVELOP A POLICY CONCERNING INSPECTIONS AT PLANTS LIKE CORNHUSKER

FSIS does not have a policy regarding plants like Cornhusker that are apt to continuously be problem plants because of their age and the type of livestock they choose to handle. Without such a policy, FSIS cannot take an aggressive, proactive stand against facilities that, through decline, permit multiple violations of standards rather than interest themselves in long-term improvements. Although we do not know of any plants that are currently as bad as Cornhusker, there are certainly many that can, through time, arrive at that state, and we believe FSIS should develop a consistent approach towards its inspections of them.

As mentioned earlier, Cornhusker operates out of an old facility and handles older animals, such as cull dairy cows, that are slaughtered generally to be processed into ground beef. Therefore, Cornhusker's operation potentially poses a greater risk to consumers than that of other plants that use newer facilities and slaughter younger, healthier animals. FSIS is obliged to control this risk by increasing its inspection efforts of the animals brought to slaughter and of the plant itself, to ensure that deteriorating structures and equipment are replaced or brought up to standard.

Cornhusker's long history of violations clearly shows that plant management was interested only in short-term corrections to long-term problems, pointing out that FSIS needs more effective methods of seeking and enforcing permanent solutions. An example of this was Cornhusker's decision not to establish any quality control over its own product. Although most other plants bear some expense of ensuring the quality of their products, Cornhusker relies on FSIS. Cornhusker has not taken the initiative in any potential area of self-monitoring, and FSIS cannot require it to do so; instead, FSIS has tolerated Cornhusker's abrogation of this responsibility. While such tolerance may be acceptable to a degree at some plants, it should not be acceptable at plants like Cornhusker.

The Department is developing a program of self-regulation called the Hazard Analysis and Critical Control Point system, or HACCP. The HACCP system, which is planned to be mandated for all plants, will require plant managers to identify critical points that must be controlled to prevent hazards from occurring. We believe such a system could be a valuable part of any policy aimed at seeking solutions to problem plants.

Program Review Division personnel told us that old facilities and difficult plant management were two indicators of plants which are likely to produce bad product. They believe there could be many more old plants still in operation. Recent special reviews have been successful in identifying problem plants. For example, after

the outbreak of E. coli poisoning from contaminated ground beef, 90 plants underwent a special review; 30 of these plants were ordered to temporarily shut down operations and 12 were placed under a special enforcement program. We believe these actions demonstrate the effectiveness of a policy that is informed and directed, as well as one that involves FSIS management thoroughly in the identification of potential problems. As our evaluation of Cornhusker shows, the problems that developed through the years at that plant continued in the absence of FSIS management's awareness and involvement.

RECOMMENDATION NO. 10

Create a profile of Cornhusker, based on available information, and compile a list of all plants nationwide that fit that profile.

RECOMMENDATION NO. 11

Establish a policy that prepares FSIS to seek solutions to plants that meet Cornhusker's profile. This policy should address such issues as the need to conduct a special review of such plants, the frequency of inspections, the enforcement of corrective actions (including the possible closure of the plants), and most especially, the degree of FSIS management's involvement in the process.

EXHIBIT A - CHRONOLOGY OF EVENTS RELATED TO SLAUGHTER PLANT OPERATIONS

- 1950 -- Plant approved for operations.
- 01/09/87 -- Dead rat found on kill floor after start of operations. Inspectors assigned to review premises after operations suspended at 9:30 a.m. More evidence was found on the same floor, including a live rat and insects underneath old equipment. Other evidence included a dead mouse and contamination in the maintenance area. Other contamination was found in upstairs storage area, and live rats were found in the basement.
- 01/10/87 -- Operations resumed at 6:53 a.m. (inspection records indicate that corrections were made). The plant submitted a nine-point plan for pest control. The nine points included steps taken to block rodent access to the plant.
- 01/17/87 -- Documents show 39 dead rats were discovered within the space of a week. The pest control contractor found rat burrows around the kill ramp outside the plant. The contractor found that the need for continual repair was obvious. Recommendations included sealing holes, repairing walls, repairing sewers and drain pipes, sealing doors, and rat-proofing windows.
- 05/13/87 -- Letter to the plant manager from the circuit supervisor cited several instances when plant employees used loud, vulgar language towards the inspectors. The letter insisted that steps be taken to prevent recurrences.
- 10/01/87 -- The circuit supervisor provided a letter to the area supervisor citing improper use of plant employee frocks and gloves, and inadequate cleaning of the boning room during lunch break.
- 04/05/88 -- Letter to the area office by the new inspector-in-charge (IIC) reported a rat seen on the kill floor. Operations were suspended and the carcasses removed from the kill floor. The old rendering room was cleaned. Materials were raised off the floor. A pest control contractor was contacted and bait stations installed. Possible entry sites were sealed.
- 01/10/90 -- FSIS inspectors noted trash and old, dirty equipment on the west side of the building which could contribute to rodent problems.
- 06/25/90 -- FSIS released a Summary Report for the circuit. Sanitation of facilities and equipment in the circuit were rated as acceptable, with variations. Cornhusker was cited because electrical wiring contained residue from previous days' use and broken product boxes were on the freezer floor. The open product was condemned, and the circuit supervisor told the IIC to check the freezer at least once a day and check drop cords during pre-op sanitation.
- 03/13/91 -- An inspector observed rat feces and shredded rope in the cellar, possibly gnawed by rats using it for nesting.
- 03/25/91 -- FSIS inspectors noted bull carcasses dragging on the floor. Plant management said carcasses would be hung higher on the hooks.
- 04/02/91 -- Inspectors noted that a plant employee dropped a front shank, dragged it on the floor, then threw it on the table. The shank was retrimmed and the plant agreed to educate the employee.

- 04/08/91 -- Inspectors noted meat products had bone fragments and feces. The products were reworked and the plant agreed to screen more carefully.
- 04/16/91 -- Inspectors noted that a plant employee saved a contaminated forequarter. The plant responded only that the problem was corrected.
- 04/17/91 -- The IIC completed a form FSIS 8110-2 for product preparation violations. The IIC found that heads were boned before the viscera was inspected. The head chain speed was reduced to that of the viscera chain.
- 04/30/91 -- An inspector observed a mouse enter the main hallway from the cooler hallway. All other cooler doors were closed, and there was no evidence of product contamination.
- 05/15/91 -- The IIC prepared a plant improvement plan because the kill floor traffic area was broken and crumbly. The corrective action plan specified the floor had to be patched or completely replaced. The plant inserted temporary patches.
- 08/08/91 -- Form 8110-2A indicated a cooler floor was broken up in two places.
- 01/21/92 -- Inspectors at a facility receiving product from Cornhusker reported that chucks and brisket areas had intestinal spillage and that 20 percent of the load was contaminated in this manner.
- 02/05/92 -- The IIC completed an entire 8110-2 form for general violations. A cooler floor was noted for crumbling. Also, unused pipes were in that cooler. Retained carcasses were in immediate contact with each other.
- 05/06/92 -- Inspectors noted that the east wall of the loading dock had holes in it and boning room rail brackets had rust and peeling paint.
- 05/21/92 -- The IIC completed form 8110-2A for pest and rodent control problems. The form 8110-2A noted trash accumulation in the dry storage area, improper storage of packaging materials, and improper disposition of discarded equipment in the returned product area.
- 06/15/92 -- The IIC completed form 8110-2 for facility and equipment violations. The review noted the boning room blueprints were not current. The cooler walls were dirty, and the dry storage area had trash in it. Corrective actions were not specified or described.
- 07/13/92 -- A plant improvement plan noted that the offal cooler ceiling trim around beams was loose and in disrepair. The plan indicated immediate repair.
- 07/28/92 -- The IIC completed form 8110-2 for product preparation violations. The review noted arm chucks of big bulls were dragged on the floor of the boning room. The product was tagged and trimmed before release. A new breaking procedure was developed.
- 08/05/92 -- The area office performed special reviews in two Omaha plants but not Cornhusker.
- 08/17/92 -- Inspectors noted high weeds throughout the plant perimeter.
- 10/29/92 -- The IIC completed an entire form 8110-2. Form 8110-2A noted that inedible room doors were locked during operations, exits were not marked properly, trash had accumulated throughout the plant, the floor was crumbling in a cooler, and boards were broken in the antemortem area. The deficiencies were included in a plant improvement plan. The plant improvement plan was resolved in December 1992.

- 12/29/92 -- The IIC completed a form 8110-2 for product preparation violations. Antemortem pin cards were not accompanying animals to slaughter. The IIC also noted sloppy carcass dressing procedures relating to dirt, hide, rumen, and ingesta contamination.
- 01/14/93 -- Inspectors observed a rat on the kill floor during operation. The slaughter line was halted for 7 minutes while the floor was hosed down with 180 degree water. The pest control contractor was notified.
- 02/08/93 -- A memo from the "Omaha Thirteen" was received by FSIS. The memo asserted that Cornhusker was a roach and rat-infested plant. The memo said the plant was filthy and that inspectors had no backing. The memo said some inspectors wanted to contact the news media. Also, the memo alleged misconduct by an FSIS employee.
- 03/04/93 -- The area supervisor completed a review of the Cornhusker pest control program. A licensed pest control firm was to monitor the program and provide services on a biweekly basis. The inspectors had not been monitoring application of insecticides and rodenticides. The service technician had not been indicating any rodent activity on service reports. The area supervisor and circuit supervisor established a new monitoring schedule. The area supervisor noted several problem areas:
1. A cockroach was found in the Government office.
 2. Rat droppings were found in several nonproduction areas, including the boiler room, maintenance shop, compressor area, salt storage area, and hide processing area.
 3. The plant's housekeeping and sanitation was inadequate.
 4. Outside doors and windows did not close properly.
 5. Unused equipment was stored in several areas of the plant.
 6. Nonproduction area walls had several holes in them.
 7. Drain covers were missing or inadequate.
- The area supervisor stated that he would return to review the plant in 2 weeks. (He later advised OIG that he was unable to do so because of other priorities.)
- 03/10/93 -- The IIC completed form 8110-2 showing facility and equipment violations. Plant management refused to sign forms 8110-2, 8110-2A or the plant improvement program. The plant improvement program required repairing a cooler floor and the deficient lighting at various points on the kill floor. Form 8110-2A also noted that the various plant lockers were rusty and had accumulated trash.
- 03/23/93 -- A Daily Sanitation Report noted open-end pipes under tanks in the tank room needed to be covered to prevent rodent nesting. The plant's response was that they would investigate.
- 03/25/93 -- FSIS inspectors at a facility receiving product from Cornhusker reported that a load of product was not in zero tolerance. Similar complaints on meat shipped by Cornhusker were made on April 8 and May 5.
- 04/06/93 -- The Deputy Administrator, Inspection Operations, received a follow-up memo from the "Omaha Thirteen." The memo said the March 3, 1993, visit by the area supervisor did not identify all rodent problems. The memo asserted that inspectors were threatened for "squealing."
- 04/16/93 -- Inspectors noted rat droppings on the third-floor hallway. The report said the plant manager stepped on the droppings and said he did not see anything.

- 05/06/93 -- The IIC completed form 8110-2 for review of pest control, storage and shipping. The IIC found the plant in compliance in both areas.
- 05/11/93 -- Five days later, inspectors noted rat droppings on the kill floor, the stairway to the basement, and the old rendering room on the third floor. Inspectors reported that none were seen by plant management.
- 05/12/93 -- FSIS inspectors at a facility receiving product from Cornhusker reported that a load of product had ingesta on most all forequarters and fecal contamination on most all hindquarters. The inspectors noted one forequarter had a handful of ingesta inside the neck area.
- 05/12/93 -- Inspectors reported rat droppings in the old rendering room and in the basement. Plant management agreed to investigate. Inspectors continued to note rat droppings over the next week.
- 05/17/93 -- **Newscast reports unsanitary conditions at the plant.**
-
- 05/18/93 -- Inspectors reported that company people killed two rats in the old rendering room.
- 05/19/93 -- The area supervisor visited the plant and found evidence of rodents adjacent to the slaughter area. Plant operations were shut down until the afternoon of May 25.
- 05/21/93 -- The IIC notified Cornhusker management that the plant would be placed in Stage I of the Progressive Enforcement Program.
- 06/01/93 -- Circuit supervisor performed an indepth review and identified approximately 100 deficiencies.
- 06/05/93 -- Plant management fumigated the plant for rodents.
- 06/07/93 -- After more evidence of rodents was found, plant management shut the plant down and fumigated the plant again.
- 06/08/93 -- OIG and personnel from the Program Review Division conducted a joint review and identified several serious deficiencies.
- 06/10/93 -- Personnel from the area office, regional office and FSIS headquarters reviewed the plant, and the start of slaughter operations was delayed until the afternoon.
- 06/18/93 -- FSIS elevated Cornhusker to Stage II, Establishments Requiring Additional Inspection Effort (ERAIE), of the Progressive Enforcement Program.

EXHIBIT B - CONDITIONS NOTED DURING ONSITE REVIEW

	Product Sanitation
1	On the kill floor, meat products were observed to be contaminated with feces and other unidentified particles, and while contaminated, came in contact with other edible organs.
2	Oversized carcasses with exposed head and tongue surfaces were dragged through the blood pit and on the kill floor. No controls for identifying such carcasses were observed.
3	Flaps hanging over door through which product entered were smeared with grease and blood.
4	Water exhaust hose contacted kill floor then contacted carcasses when lift raised.
5	In the offal area, product ready for packing was observed with unidentifiable particles.
6	Water from the head rail wash station splashed contamination from kill floor onto forequarters of hanging carcasses.
7	In holding coolers, beef sides were observed with unidentifiable particles of contamination.
8	During a pre-op sanitation inspection we observed several meat storage containers in use which were contaminated with residue from previous days' activities. Also, residue from previous days' activities was observed on knives, hooks and other plant equipment ready for use throughout the plant.
9	We observed dirty ox tails.
	Outside Premises
1	The grounds were overgrown with high grass and weeds, which showed the plant did not have an effective grounds maintenance program.
2	Junk was piled next to the main road and timbers, rocks, and straw were piled around the plant. This debris could harbor rodents.
3	Uncovered waste in a garbage can was attracting flies.
4	Wood debris was scattered in the loading area.
5	Three doors had space for vermin to enter.
6	Deep holes with standing water were noted in several areas around the plant.
7	Several lots of unused equipment were stored behind the plant and adjacent to the pens.
	Plant and Equipment
1	At least five windows opening onto the kill floor had large gaps, allowing flies to enter.
2	Machine shop screen was cage mesh, allowing pests to enter.
3	Opening around door going from the kill floor into machine room allowed pests to enter.
4	Boning room table made of a plastic material had numerous deep cuts and plastic shavings.
5	Drain covers were loose or broken, which could cause rodent or safety problems.

6	The plant had numerous dead-end water pipes, which could serve as reservoirs for bacteria.
7	A knife sanitizer was not provided in the pre-boning trim area, and sanitizer were being used at temperatures inadequate to ensure sterilization in several areas.
8	The coolers had dripping condensation and numerous cracks in the floor.
9	Kill floor inedible barrels were in disrepair.
10	The freezer area that held product set aside by FSIS for further testing consisted of four chain-link "walls" held together at the corners by baling wire. Although the front cover had a lock, the back corner was open, allowing ready access.
11	There were rusty electrical fixtures and florescent lights with broken covers above product.
12	The light above the work line was 25 foot-candles instead of the required 30.
13	There were numerous cracks in floor and wall, and gaps in supports and corners.
14	The hallway outside inspection office had 1 foot-candle of light.
15	Heavily beaded condensation was observed on overhead refrigeration units in several areas.
Plant Management/Supervision of Plant Employees	
1	The plant manager confronted the IIC in a loud and threatening manner concerning an inspection decision.
2	In the slaughter area, an employee wearing street clothes was trimming beef carcasses. Rusty hooks, ready for use were stored at this same location. Some hooks were in direct contact with employee's contaminated work boots. A knife, ready for use with exposed product, was stored on the floor of an employee's work station.
3	Employees left meat in "wash only" sink during lunch break.
4	Employees threw trimmings on the floor throughout the plant.
5	Over the lunch period, employees left aprons/gloves on the processing line and over product. Knives were left in contact with the platform where employees stand.
6	In the freezer, employees left several partially filled unlabeled boxes with unidentifiable product. Some unmarked plastic-wrapped packages of unidentifiable product were stored on top of boxed product.
7	In the offal area, several beef hearts with illegible marks of inspection were observed.
8	In the dry storage room, plastic bags and rolls of exposed packaging material that would come in contact with product were stored on and in contact with obviously dirty surfaces.
9	In the freezer, a roll of packaging material that would come in contact with product was stored on a dirty wooden pallet.
10	In the edible offal packaging room, meat and fat residues from the previous days' activities were observed inside several meat trays.
11	Unopened cardboard boxes and bins were stored directly on the dirty floor of a trailer.
12	An employee had a soft drink in the processing area. (Food is forbidden in this area.)

EXHIBIT C - FSIS RESPONSE TO DRAFT EVALUATION

United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 3 1993

TO: James R. Ebbitt
Assistant Inspector General
for Audit
Office of Inspector General

FROM: H. Russell Cross *H. Russell Cross*
Administrator

SUBJECT: Response to the Office of Inspector General's
Evaluation of Inspection Operations, Cornhusker
Packing Company, Omaha, Nebraska

Thank you for providing the Food Safety and Inspection Service (FSIS) the opportunity to review your draft evaluation report. We appreciate the report's candid insights concerning Cornhusker's failure to meet Federal meat inspection requirements and your observations about the need for FSIS to improve communication throughout its chain of command.

FSIS is committed to an aggressive two-track approach to inspection reform. The two-track approach allows FSIS to operate the current inspection system at its maximum level within Track I, while planning an inspection program of the future (Track II). We will incorporate the immediate and long-term recommendations of your report into this reform activity. We intend to address your findings and recommendations through the Pathogen Reduction Program, our restructuring activities, and improved program review, supervision and enforcement.

The Pathogen Reduction Program is a working model of the two-track approach, since it is a focused program aimed at finding immediate solutions to current problems and developing entirely new regulatory approaches for the future. The control of pathogenic microorganisms is and always has been an implicit goal of the meat and poultry inspection program. However, in recent months, FSIS has undertaken steps to strengthen public health protection by squarely facing the risks posed by microbiological pathogens in the food supply.

Although we believe problems identified by your report are more directly addressed by improved supervision and management, we accept your recommendation to enhance microbiological monitoring to improve food safety surveillance. We have

James R. Ebbitt

2

several activities in the Pathogen Reduction Program which will be piloted shortly that will give us more experience with introducing microbiological testing as an inspection tool. Projects that are moving toward planned implementation this year are: the cow/bull microbiological baseline survey, the disabled cow pathogen survey, and the ground beef pathogen survey. We are also developing pilot projects for microbiological verification of critical control points as part of the Hazard Analysis Critical Control Point initiative. Also, the Pathogen Reduction Program has added a new dimension to its efforts relating to pre-operational sanitation--a microbiological monitoring component. A team is being formed and efforts will be underway this calendar year to gather information and trial some of the available commercial kits which might be used to supplement current organoleptic inspection techniques.

In addition, FSIS has determined that organizational changes are needed to improve headquarters-field communication and equip the Agency for the future. We are currently undertaking a two-phase restructuring of the headquarters office. Earlier this month, I reassigned the senior FSIS managers to provide new perspectives for changes that are needed now and fresh ideas to plan for the future (Phase I). We are also actively planning for reassignment of programs and employees throughout FSIS (Phase II). Among the important objectives for this restructuring are: improved communication between field and headquarters personnel; clear, uniform policies and decisionmaking processes; and stronger application of program standards.

Although we will not complete plans for this restructuring until this fall, we see an urgent need to revitalize internal review activities and have proceeded with this change in advance of the reorganization. On July 11, FSIS announced that a new senior executive position has been established for Review and Assessment. The reassignment of the Program Review Division to the new Review and Assessment office provides direct reporting to the Administrator of plant review results and followup investigations of the causes of breakdowns in inspection effectiveness.

Inspection Operations and the Review and Assessment office are currently working together to identify plants for priority attention and develop protocols for systematic reviews. FSIS intends for these reviews to be conducted jointly by a program reviewer and an inspection official who have authority to direct corrective action. Currently, FSIS plans to begin a 90-day trial of the new review and assessment program in mid-to-late August.

James R. Ebbitt

3

A special internal assessment team will also be established to conduct followup investigations and audits, when problem situations are identified through reviews, inspector referrals, and other reports. The establishment of the new Review and Assessment office will enable FSIS to independently verify and respond to complaints and allegations and assure appropriate referrals to the Office of Inspector General. FSIS will develop a profile of techniques and conditions prevalent in "excellent" plants and circuits to determine how improvements can be adopted nationwide. We will also develop a model of plants where deficiencies jeopardize FSIS public health objectives. Situations described in your report can serve as a component of this profile. These models can then be used by inspectors, supervisors and reviewers to address serious problems before they get out of hand.

Inspection Operations intends to reemphasize the Progressive Enforcement Program, work with the inspectors' union to consider inspector rotation policies as they relate to program integrity concerns, and revitalize its systems of reviews by line supervisors and staff officers from the Area and Regional Offices. While we believe that requiring the Inspector-in-Charge to conduct in-depth reviews has value in strengthening accountability, it is clear that stronger oversight from the region and area levels is needed to be sure corrective actions are being taken in problem situations. Similarly, these reviews can be used as training opportunities, to reemphasize the proper use of Progressive Enforcement Actions, and to strengthen communication and reporting.

With regard to the specific concerns at the Cornhusker plant, the Deputy Administrator, Inspection Operations, traveled to the plant for a first-hand review during the last week of July. He has reported to me that progress under the Progressive Enforcement Program is satisfactory, but continued emphasis is needed to ensure ongoing compliance.

In summary, FSIS intends to move quickly and decisively to ensure that our management practices do not permit repetitions of the inadequate response to plant compliance problems--documented in your report. All of OIG's recommendations can be incorporated into improvements that we have set in motion for pathogen reduction, program review, and stronger supervision and oversight of the plant inspection processes.

Informational copies of this report have been distributed to:

Administrator

Attn: Agency Liaison Officer (6)

General Accounting Office (1)

Office of Finance and Management

Director (1)

Audit Liaison Office (1)

William M. Layden

FOOD SAFETY: A PATCHWORK SYSTEM

Despite a sheaf of laws and regulations, the government still lacks any comprehensive food safety policy.

ASSUME THAT THE 250 million people in the United States eat three meals a day. That means the nation's food safety policies directly affect Americans nearly 274 billion times a year—not including snacks.

These policies have generally served us well. Food is relatively cheap, plentiful, and wholesome. In fact, the United States has generally been thought to have the safest food supply in the world.

WILLIAM M. LAYDEN is a senior evaluator in the Food and Agricultural Issue Area of GAO's Resources, Community, and Economic Development Division.

But perhaps it is not safe enough. Every year, enough contaminated food falls through the safety net to kill at least 9,100 Americans and make at least 6.5 million others sick, according to researchers from the Centers for Disease Control (CDC).¹ And that's only acute illness; the extent of long-term disease related to food is unknown. In addition, the social costs of food-borne illness, such as medical expenses and lost productivity, are sizable, estimated to reach between \$4 billion and \$8 billion annually.²

The problem is not simply that individual food safety laws are not achieving what they were



THE FOOD SAFETY SYSTEM

designed to achieve. Rather, it is that most of these policies were created one by one to address specific problems, not in concert to achieve consistent, broad-based goals. Viewed in its entirety, the existing regulatory structure is inefficient, cumbersome, and costly.

More important, it has not kept up with today's needs and concerns. Changes in scientific and medical knowledge, trade and technology, and consumer demographics and behavior have expanded the definition of "safe food" in ways that were never envisioned when the policies were

the Department of Health and Human Services. The other is the U.S. Department of Agriculture (USDA), which includes five agencies that address food safety issues.

The federal government involves itself in virtually all stages of food production and marketing, from raw agricultural commodity to finished product. It sets standards for specific foods, approves certain food preparation equipment and processes, inspects facilities and products, sets legal limits for chemicals in food and tests food for compliance; regulates labeling and packaging; monitors state and local inspection programs; conducts research and consumer education efforts; takes action against illegal products; and monitors food-borne illnesses and other problems.

Obviously, this is a mammoth effort. Some 6,100 meat and poultry plants and more than 50,000 food establishments are subject to inspection by USDA or FDA. About 537,000 commercial restaurants, 172,000 institutional food programs, 190,000 retail food stores, and 1 million food-vending locations submit to state and local inspection with FDA oversight. And the government keeps tabs on more than 70,000 separately labeled food products, 23,000 pesticides, 12,000 animal drugs, and thousands of additives—as well as \$22 billion worth of food and agriculture imports.¹

Its magnitude notwithstanding, this regulatory system did not develop under any rational plan. Programs emerged piecemeal, typically in response to particular health threats or economic crises. The earliest federal food safety laws, passed in the late 1800s, addressed such obvious problems as filth and fraud—for example, preventing manufacturers from adding impure or imitation ingredients to such products as tea and butter. Regulations were also designed to promote trade; for instance, meat and poultry inspection was introduced to verify the wholesomeness of meat exports. The first comprehensive federal food safety laws, the Food and Drugs Act of 1906 and the Meat Inspection Act of 1907, were intended to exclude misbranded or adulterated products from interstate commerce.

Over the course of this century, food production grew from a relatively simple, localized, farm-based industry into a multibillion-dollar enterprise. As food production and processing moved from the

The nation's food safety laws were created one by one to address specific problems, not in concert to achieve consistent, broad-based goals.

created. In turn, the public has begun to raise legitimate questions about the government's ability to ensure the safest possible food supply.

Many Americans have begun to realize that their outdated food safety system is not giving them their money's worth, and the last two decades have seen many calls for reform. But the government must do more than simply improve existing programs. Rather, policymakers need to rethink the nation's overall approach to food safety regulation. Only when they define what role the government should play in food safety will they be able to determine what steps to take next.

A century's worth of rules

Although growers, manufacturers, and retailers retain primary responsibility for the safety of their products, the federal government, in cooperation with state and local governments, keeps watch over the industry. Altogether, 12 federal agencies spend about \$1 billion a year to ensure the safety and quality of the food we eat.¹ Two organizations account for most of that spending: One is the Food and Drug Administration (FDA), which falls under

home to the factory, the responsibility for ensuring food safety shifted away from consumers to processors, retailers, and—in particular—government regulators, whose role increased substantially.

At the same time, scientists learned that food could be contaminated not only with visible filth or impure fillers, but also harmful microorganisms (such as bacteria, viruses, and fungi), parasites (such as tapeworms), intentionally or unintentionally added chemicals (such as pesticides, animal drugs, flavor and color additives, industrial chemicals, or environmental contaminants), and natural poisons (such as the toxins in some fish). As understanding of food-borne hazards grew, so did concerns over food safety. Addressing one new worry after another, legislators amended old laws and enacted new ones. Today, a century's worth of such rules constitutes the complicated network that is our food safety system.

As food production moved from the home to the factory, the responsibility for ensuring food safety shifted away from consumers to processors, retailers, and the government.

Inconsistency and inefficiency

The food safety laws have unquestionably improved the safety and purity of the nation's food supply. But overall, the system suffers from its longstanding lack of coordination. The dozen federal agencies involved in food safety operate under different mandates and definitions. Too often, they duplicate efforts in some areas while ignoring others entirely. More important, their standards of risk are inconsistent with one another.

The most obvious problems lie in the division of responsibilities between USDA and FDA. For the most part, USDA oversees products containing

meat and poultry, while FDA regulates all other food products. The arrangement is not quite as simple as it sounds. For example, the two organizations share jurisdiction for egg products. FDA also is responsible for products containing less than 3 percent raw meat or poultry, as well as those containing less than 2 percent cooked meat or poultry. And both organizations monitor domestic and imported food for potentially harmful chemicals, such as pesticides, animal drugs, and environmental contaminants.

Yet these two organizations operate under substantially different statutory mandates. For instance, USDA carries out a massive "continuous inspection" program at slaughterhouses, which by law may operate only when one of the department's 7,350 field inspectors is on duty. USDA also inspects all meat and poultry processing plants daily. In contrast, FDA inspects facilities under its jurisdiction, on average, once every three to five years. Due in part to budget constraints, FDA and state inspections cover less than one-fourth of the nation's 50,000 food manufacturers, packers, processors, and warehouses each year.

The differences in the two organizations' approaches mean that food products that pose similar risks may receive widely varying scrutiny. For example, canned soup containing more than 2 percent meat poses essentially the same risk of contamination as canned meatless soup. In both cases, the health hazards rest not with the soup's ingredients, but with the canning process. Yet USDA conducts daily inspection of the plant producing the soup with meat, while FDA may visit the plant producing the meatless soup only once every few years. Even without knowing what level of supervision is actually necessary, any observer can see that something is wrong: Either USDA is wasting its time and money in daily inspections, or FDA is potentially allowing dangerous products to reach the market.

Even as the inspectors concentrate on some products, they ignore other areas of equal or greater concern entirely. Fish—especially shellfish—caused 21 percent of all food poisoning cases arising from meat, fish, or poultry reported to CDC between 1978 and 1987.²⁶ Yet seafood is not subject to mandatory federal inspection. In other words,

The dozen federal agencies involved in food safety operate under different mandates and definitions. Too often, they duplicate some efforts, while ignoring other areas entirely.

the same system that requires continuous inspection of chicken practically ignores tuna.

The incongruities between USDA and FDA extend well beyond their inspection methods. For example, meat and poultry products must have a USDA stamp of approval for interstate sale, but food products under FDA jurisdiction generally require no pre-market certification. USDA reviews construction plans for all manufacturing facilities for meat products, but non-meat food producers are not required to notify FDA about a plant's construction, or even its existence. And while USDA has legal authority to examine company records, FDA does not. As early as 1972, GAO noted that this impaired FDA's ability to protect the public.⁷ Other GAO and congressional reports have suggested that FDA needs additional authority to halt the distribution of questionable products and to order recalls.⁸

Over the last 20 years, many investigators have documented—and criticized—the inconsistencies of the existing arrangement. The Senate Committee on Governmental Affairs reported in 1977 that the division of responsibility between USDA and FDA “has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex. . . . There is no rationale, other than a historic one, to justify maintaining two separate, inconsistent, and costly systems for inspecting and otherwise regulating production of processed foods.”⁹

While the division between USDA and FDA provides the most obvious example of disarray, conflicts are evident throughout the food safety

system as a whole. For instance, FDA's proposed new labeling rules would not apply to food advertising, which is controlled by the Federal Trade Commission (FTC). That means that companies may soon be prohibited from making certain claims on food packages, yet still make those claims in ads. Another example is cancer policy. FDA and the Environmental Protection Agency (EPA) follow contradictory standards, mandated by separate laws, for determining the maximum level of cancer-causing chemical residues allowed in various food products.

Federal agencies have developed at least 50 formal agreements to coordinate their roles in regulating food. But GAO and others have shown that many of those arrangements don't work. Little has changed since the Senate Governmental Affairs Committee's 1977 report cited “an unrealistic demand for close cooperation between agencies which proceed under substantially different statutory direction and philosophies of regulation.” In some cases, the report added, uncertainty over jurisdictions “has led to an excess of deference and the failure of either agency to act effectively in the face of a regulatory need.”¹⁰

Recent coordination between USDA and FDA on the new food labeling regulations probably reflected in part the fact that USDA Secretary Edward Madigan had helped shepherd the law through enactment when he was in Congress in 1990. Such cooperation is not the norm. This year, GAO found that USDA and FDA failed to work together in at least two other important areas: development of a database on pesticides and efforts to control salmonella.¹¹

USDA and FDA do not work well with each other or with the other agencies that share responsibility for food safety. On an even more basic level, neither USDA nor FDA has its own house in order. GAO reported in March 1991 that USDA lacks a comprehensive food safety policy and plan. That means not only that different USDA agencies may

be working it cross purposes, but also that USDA's missing opportunities to link its various agencies work. For example, USDA's agency for animal health (the Animal and Plant Health Inspection Service) could be working with its agency for human health (the Food Safety and Inspection Service) to control animal infections that can contaminate human food.

USDA and FDA do not work well with each other. As the active agencies concerned in food safety. One does or more research neither USDA nor FDA has the resources to do it.

To add to USDA's internal confusion, the department must play two roles—promoting agriculture and protecting the public. Since its creation in 1962, USDA has concentrated on helping the agricultural industry produce a cheap and plentiful food supply. But its emphasis on the health of the industry may overshadow its responsibility to ensure the health of the consumer. Critics argue that industry pressure can inhibit USDA from working more aggressively to reduce food contamination or encourage alternative agriculture practices that lessen pesticide use.

This issue drew media attention in April 1993 when USDA decided to postpone introducing the "Faring Right Pyramid" as a replacement for the "Four Basic Food Groups," a traditional consumer dietary guide. One goal behind the pyramid was to persuade consumers to eat fewer high-fat, high-cholesterol meat, dairy, and egg products—the very products that USDA has traditionally promoted. While the Secretary stated that the pyramid was withdrawn because it had not been tested sufficiently among children and low-income Americans, others saw the move as evidence of USDA's conflicting roles. After conducting more tests,

USDA adopted a slightly altered version of the pyramid in April 1992.

USDA suffers from a different problem. It is joined beneath several covers: it coordinates with the Department of Health and Human Services (HHS). Although USDA can share cover board, drugs, and medical devices affects USDA's power to control drugs, the agency's expertise is less than other agencies, such as the Federal Food, Drug, and Cosmetic Administration (FDA) that directly controls consumer health issues. According to a 1990 report from the House Committee on Education and the Labor Committee's chair, former FDA Commissioner David A. Edwards, "FDA's efforts in regulating drugs, such as essential drugs, birth control, vaccines, and scientists' equipment facilities and equipment, arranging for information, travel and production, publications or public health. Such competence, the committee maintained, allows FDA authority and prevent it from carrying out its responsibilities."¹⁰

Unplanned obsolescence

The disarray of the food safety system has not gone unnoticed. Bills to correct perceived problems have cropped up occasionally, and Congress is debating some of these issues now. Still, it is becoming increasingly obvious that incremental attempts to shore up weak points won't address an underlying problem of the system—its inability to adapt to changing circumstances.

While the food safety system was initially designed to find and deal with such problems as outright fraud or grossly unsanitary practices, it is less well-prepared to address the troubles of most importance today. Scientific understanding of food-borne hazards, technology for producing food, consumer demographics and eating behavior, and

the public's expectations of the system have all changed since the major links in the network were established. That network, however, has failed to keep pace with these changes.

New food-borne threats

Of the various sources of food contamination, microbes probably pose the greatest risk to human health. Harmful microbes in food cause nearly all cases of acute food-borne illness in the United States each year. Because many cases go undiagnosed, the actual figure is probably much higher than the conservative figure of 6.5 million annually—at least 24 million, according to an estimate by officials at FDA.

Incremental attempts to shore up weak points won't address an underlying problem of the system: its inability to adapt to changing circumstances.

Most people have heard of salmonella. But scientists have lately identified other harmful organisms, such as listeria and campylobacter, as serious threats. That is partly because scientists have better ways of detecting microbes, but it also reflects trends in food distribution that leave products vulnerable in new ways. For example, we depend on refrigeration to keep food safe in transport, but the listeria bacterium can survive refrigeration. Each year, listeriosis strikes about 1,850 Americans, nearly one-fourth of those people die.¹⁸ Similarly, campylobacter, the leading cause of bacterial diarrhea in the United States, tends to cause illness only when it reaches high levels in food. Developments in packaging that allow longer food storage may enable the bacteria to grow to dangerous proportions.

Even more worrisome is the appearance of new or stronger strains of contaminants. A generation ago, an uncracked egg was assumed to be a bacteria-free package; legislators responded by requiring cracked eggs—potentially infected with

salmonella—to be used only in cooked products, because cooking destroys salmonella bacteria. Today, however, at least one strain of salmonella is able to pass from an infected chicken to a developing egg, so that eggs perfect to the eye might still be contaminated. Increased use of antibiotics in meat and poultry may also encourage the development of resistant strains of bacteria.

While scientists believe microbes are today's chief food-borne threats, public attention tends to focus on pesticides, animal drugs, and other chemicals in food. Chemical residues may not make individuals fall ill immediately, but some people suspect them of causing cancer, birth defects, and other problems.

These types of contaminants can provoke outrage far out of proportion to the risks they pose. That is partly because many Americans view chemical contamination as an unnecessary risk imposed on an unsuspecting population by food manufacturers who profit from the use of the chemicals. This perception sufficed to prompt episodes in 1989: first when consumer groups objected to the use of the pesticide Malathion apples and later when import inspectors found some Chilean grapes tainted with cyanide. While no one became ill in either case, both episodes damaged consumer confidence and caused severe losses in the marketplace.

Yet for the most part, USDA's methods for inspecting meat and poultry cannot detect microbial or chemical contamination. Standard inspection procedures—smelling, feeling, and looking at the product—date from an earlier era when easily identifiable conditions, such as obvious disease or spoilage, were considered the major dangers of these foods. But today, such visible problems are minimal compared to the invisible threats, which can be detected only through laboratory analysis. USDA's grading standards for produce are equally out of date, relying on criteria that are mostly cosmetic and therefore may encourage excessive use of pesticides.

Even if they had the resources to try, USDA and FDA could not identify all foods with illegal chemical residues and keep them from reaching

the consumer. The government has no useful methods for detecting many of the residues it is supposed to monitor. Even where detection is possible, there are simply too many products to examine and too many contaminants to check for in the limited time before the product is sold and eaten. The government is seeking better ways of sampling and testing for residues. But for now, government inspection may provide a false sense of security to those consumers who believe it means products are free of all contamination.

Improved technology

Technological advances in agriculture and the food processing industries have made it possible to offer a larger population a food supply that is cheaper, more varied, and more convenient than in the early 1900s. Yet some of the same tools that have dramatically expanded agricultural production—pesticides, fertilizers, and animal drugs—have themselves become cause for concern. Recent rules meant to ensure that newly introduced substances are safe to use have had the unintended effect of

worrisome in modern plants, where one infected chicken can swiftly contaminate hundreds of other birds processed with the same equipment.

Better storage and transport means that food moves farther and faster than ever before—and, in turn, that a single source of contamination can affect more people in a larger area and in a shorter period of time. Given the sheer quantities of food in production, even small risks can cause harm on a huge scale.

In general, technology is raising new questions faster than regulators can answer them. For instance, some consumer advocates worry that new genetically engineered food products may cause unforeseen harm. While FDA is authorized to approve food additives, it has no comparable authority to review new *foods* before they enter the market. This issue drew attention in 1991, when Calgene, a California biotechnology firm, asked FDA to informally concur with its plans to market a tomato genetically engineered to remain firm during shipment. FDA is still reviewing the case.

Changed consumer behavior

As the demographics of a population change, so does its risk of disease. People who are older or immune-compromised—two rapidly growing groups—are more vulnerable to food-borne illness than younger, healthier people. Eating patterns also shift with demographics. For example, Americans eat almost 60 percent more seafood now than they did 10 years ago, partly because of growing numbers of minorities and senior citizens, who consume high proportions of fish.¹⁴ Risk has increased accordingly, as seafood is highly susceptible to contamination.

Changes in lifestyle make a difference, too. To meet consumer demand for low-processed, ready-to-eat foods, manufacturers are packaging more types of food than ever in convenient forms. Consumers, taking for granted that all packaged foods are safe, may overlook directions to refrigerate containers or to stir foods during microwave

Food inspection procedures date from an era in which visible disease or spoilage were considered the chief dangers. Today's invisible threats can be detected only through laboratory analysis.

discouraging the development of safer chemical products; manufacturers and consumers instead stick with products that were approved under older, less stringent standards.

Mechanical improvements have introduced food safety problems, too. Traditional inspection methods cannot keep pace with high-speed equipment that allows only a few seconds for inspectors to examine each piece of meat and poultry. And the inability of inspectors to detect microbial contamination becomes even more

cooking—steps necessary to control microbes in certain products.

The trend toward eating out adds to risk as well. USDA estimates that almost half the money consumers spend on food now goes to meals and snacks away from home. At the same time, budget constraints are limiting state and local inspections of retail food operations. Underinspected establishments, such as self-serve counters at grocery stores, run an increased risk of food contamination.

Americans seem not to enough appreciate the importance of cooking and storing food properly. FDA estimates that 50 percent of food-borne illness results from unsafe food handling in the home.

And much of the responsibility rests with consumers themselves. Even as Americans have become further removed from the sources of their food, they have developed what may be a dangerous dependence on others to ensure the safety of their food. In general, Americans seem increasingly unaware of the importance of cooking and storing food properly to destroy microbes and keep contamination from spreading. FDA estimates that 50 percent of food-borne illness involves unsafe food handling in the home.

Greater expectations

In this century, diseases caused by nutritional deficiencies—such as beriberi, pellagra, and scurvy—have almost disappeared. However, in their place, we have seen a rise in problems linked to dietary excess, such as heart disease and cancer. While once people worried about getting enough calories, protein, and fat from their food, health professionals now warn against eating too much of these substances, especially fat.

In the wake of this reversal, some federal food quality standards appear particularly outdated. For instance, under USDA's decades-old ranking system, the "best" grades of meat—Prime and Choice—are those with the highest proportion of fat. Similarly, the definitions for butter, cheese, and other foods prescribe certain levels of fat, which means that low-fat versions must be labeled as "imitations." The proposed labeling changes include revisions in some of these standards.

Growing evidence suggests that overindulgent behavior has far more impact on health than food contamination does. For example, various studies estimate that perhaps one third of all U.S. cancer deaths may be diet-related. In contrast, chemical additives in food—such as color forms and preservatives—may contribute to less than 1 percent of cancer deaths. In other words, modifying dietary behavior might contribute more to public health than eliminating all intentional additives from food. It remains an open question exactly what role the government can or should play in overseeing Americans' food choices—and whether consumers will demand that the government try to restrict "unhealthy" foods as well as "unsafe" ones.

Broad-based reforms

The problems of the food safety network are far too broad and varied to be solved with narrowly targeted corrections. Real improvement will require large-scale reforms. These two steps would make a good beginning.

Restructure the network to work efficiently and consistently. Any change should begin with the two organizations that share most of the responsibility for food safety: USDA and FDA. The government has already taken some steps to clean up internal problems, in response to GAO's

The problems of the food system are not an individual and isolated, but a global and interrelated regional, national, and international issues. Reducing government's role requires a long-term solution.

recommendations, the Secretary of Agriculture announced in September 1991 that he would name a commission to consider how USDA can better manage cross-cutting issues within its own walls.

As for FDA, the 1991 FDA's Committee report recommended elevating the agency's status within HHS to par FDA on a par with its corresponding regulatory agencies such as EPA, FTC, and the Occupational Safety and Health Agency. The committee also proposed that if HHS failed to act, Congress should consider restructuring FDA as a free-standing executive agency. HHS and the administration, however, received that proposal with little enthusiasm. Meanwhile, Congress is considering legislation to enhance FDA's enforcement authority.

Resolving the internal problems of USDA and FDA is just the beginning. Policymakers must also deal with the historically inconsistent treatment of food risks by the dozen agencies involved in food safety, as well as the ways in which they work—or don't work—together.

One alternative would be to consolidate food safety functions into a single agency, with all activities carried out within a unified framework. In fact, in 1977, the Senate Committee on Governmental Affairs recommended uniting federal responsibility for food regulation under FDA and elevating that agency's status within its parent department: "Appropriate overall organization of the regulatory structure can help government to operate at maximum efficiency and economy, avoiding conflicts and duplication of effort," the Committee noted. "This is especially necessary in

times such as the present when money for new programs is in short supply, and the only opportunity to finance new initiatives is to save resources by reducing inefficiency, waste, and duplication of unnecessary efforts."²⁰

In response to that report, GAO stated that the concept of consolidation had some merit in general, but that more work was needed to determine whether to consolidate food safety responsibility in FDA or create some new federal entity. "That remains the case," although consolidation has been suggested many times in the years since.

Redesign the inspection system to place more responsibility on industry.

Government's traditional approach to food safety is to inspect finished products. But as FDA has noted, "Quality cannot be inspected after the fact. If a quality product is to be produced, then the basic manufacturing system must be designed to ensure its production."²¹

The existing inspection system is not only expensive and inadequate, it is also counterproductive. Fifteen years ago, GAO found that the mere presence of USDA inspection may "discourage industry from building quality and safety into its operations, because plants have come to rely on inspectors to provide quality control."

GAO and others have long recommended that daily inspection of meat and poultry processing plants should be phased out. Instead, government must formally pass that responsibility and trust to industry. A recent internal USDA report also affirmed the need to shift responsibility to industry for producing quality meat and poultry products and to re-direct federal resources to achieve the mentioned objectives.²²

Under proposed arrangements, the government would continue to set standards for food, but it would require industry to develop its own quality control systems. Federal regulators would approve and audit those systems and conduct occasional

unannounced inspections, penalizing manufacturers for noncompliance when necessary. Such a strategy would make far better use of limited resources now wasted on ineffective inspections.

However, FDA and USDA are finding it difficult to shift the burden onto industry. In 1988, under direction from Congress, USDA proposed reduced inspections at meat and poultry processing plants, but the proposal never got beyond preliminary testing. FDA would like to adopt similar approaches, but is handicapped because it may lack the necessary authority over industry.

No system can guarantee the purity of every bite Americans take. The system needs to ensure some level of safety while being flexible enough to respond to changing circumstances.

Rethinking the system

Such reforms as reorganizing the food safety network and restructuring the inspection system would help. But as useful as these changes might be, they would, like earlier improvements, provide only temporary relief unless they were made in concert with a comprehensive national policy for food safety.

To begin with, policymakers need to define the federal government's mission concerning food safety and quality. Because no system can guarantee the purity of every bite Americans take, the overall goal cannot be to seek an unattainable, immovable ideal of absolute protection. Rather, the system needs to ensure some level of safety while being flexible enough to respond to changing circumstances and expectations.

In setting objectives, policymakers need to weigh the importance of known physical risks (such as bacterial contamination) against perceived risks (such as chemical residues that may pose relatively little hazard but still arouse consumer outrage and fear). They must also determine just what "safe food" means. Is it "food that will not make you sick," or "food that does not pose long-term hazards," or "food that is good for you"? At some point, the desire to protect individuals from danger clashes with personal liberty and responsibility, not to mention free enterprise. This issue will become particularly apparent as federal attempts to screen out harmful substances evolve into efforts to promote "healthy" eating.

Given a clear mission and objectives, the next step will be to decide how much the nation can and should invest in food safety and quality. If current trends continue, funding will only get tighter: real federal spending for food safety agencies has generally decreased since 1980, while work loads have grown. Still, adding funds will not in itself solve the problems. Policymakers must focus their efforts on getting the most from the nation's investment in food safety and quality—a process that almost certainly will involve reorganizing the system's approach and structure.

Finally, the government must develop ways to measure its progress. At present, regulators generally monitor an agency's performance by keeping track of what it does, not what it achieves. For example, we know how much meat and poultry is inspected, but we have no data on whether that inspection really prevents illness. Without real measurements, no one can tell whether the nation is spending its food safety resources wisely.

These issues have yet to be resolved, and the solutions are by no means clear or easy. Each question raises new ones, ultimately, food policy touches dozens of other major issues, ranging from international trade and environmental pollution to agriculture and public health. But at base, it

If policymakers truly want to establish a consistent and cost-effective approach to ensuring the safety of all foods, they must break away from the legacy of disorder and rethink their goals.

policymakers truly want to establish a consistent and cost-effective approach to ensuring the safety of food, they must break away from the legacies of disorder and rethink their goals. Without that, any reforms will simply further confuse the complicated patchwork we call our food safety system. ■

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APPENDIX 3.—ADDITIONAL MATERIAL FOR THE NOVEMBER 19, 1993, HEARING RECORD

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CHAIRMAN

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ONE HUNDRED THIRTH CONGRESS

Congress of the United States House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

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October 4, 1993

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MAJORITY—222 (D-105)
MINORITY—222 (R-107)

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Mr. Secretary:

In the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations Subcommittee of the House Committee on Government Operations is reviewing the need to revamp the federal food safety system. In furtherance of this review, I am pleased to invite you to testify on the U.S. Department of Agriculture's (USDA) meat and poultry inspection program at the Subcommittee's first in a series of hearings entitled, "Reinventing the Federal Food Safety System." The hearing is tentatively scheduled for the last week in October, 1993, and we will inform you of the exact date, time and location of the hearing in the near future.

Specifically, I would like you to address the following issues:

- (1) What are the primary risks to public health associated with meat and poultry? Do these risks differ significantly from those posed by other food products, such as buffalo meat, shellfish, or low-acid canned food? If so, how? What rationale exists, other than an historical one, to justify differences in the approach and intensity of the federal government's inspection and regulation of different food products and commodities?
- (2) To what extent is the present meat and poultry inspection system designed to prevent, control, reduce, or eliminate the primary risks to public health associated with meat and poultry products? What are the gaps and limitations in the present system's ability to manage these risks? To what extent is the present system designed to control animal diseases and economic adulteration?
- (3) What is the status of USDA's efforts to reform and modernize the meat and poultry inspection system?

Secretary Espy
October 4, 1993
Page Two

- (4) What more needs to be done to further reduce and prevent the risks to public health from meat and poultry products?
- (5) What would an optimal federal food safety system look like? What should be the major components and guiding principles of an optimal system? What options exist for developing and implementing such a system?
- (6) Should the federal government revamp its food safety system and, if so, how?

To adequately prepare for the hearing, I request that your Department fully brief Bill Layden, a member of my staff, on or about October 15, 1993, on the following matters.

- (1) The status and results of USDA's investigations into the cause, source, and incidence of meat contaminated with E. coli 0157:H7, including the results of any on-farm investigations.
- (2) The status of and plans for all USDA initiatives to reform the meat and poultry inspection programs, including Tracks I & II; the Pathogen Reduction Program; identification and trace-back of animals; on-farm pathogen reduction and intervention programs; the national microbiological baseline study; the development and validation of rapid tests to detect E. coli 0157:H7 and other pathogenic microorganisms; development and implementation of a mandatory Hazard Analysis Critical Control Point inspection approach; implementation of safe handling and cooking labels; the results of USDA's special review of beef slaughter plants; and efforts to estimate the risks of pathogenic microorganisms throughout the food system using dose response models.

For each initiative, please provide a brief description, the estimated level of effort needed to achieve the objective (e.g., staff years and resources), the projected time tables to completion, and results to date.

- (3) The level of effort USDA has expended to research, inspect and regulate pathogenic microorganisms in/on meat and poultry, especially the development of rapid detection tests, since the 1985 National Academy of Sciences' report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program.
- (4) The status of USDA's research and regulatory efforts concerning irradiation of meat and poultry.
- (5) The status of USDA's efforts to educate and inform consumers about the proper handling and cooking of meat and poultry.

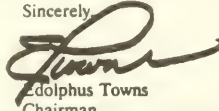
Secretary Espy
October 4, 1993
Page Three

Please arrange to have 50 copies of your prepared statement delivered to the Subcommittee office (room B-372 Rayburn) by no later than 5:00 p.m., two business days before the hearing. Such advance submission is required in order to give the Members an opportunity to study your statement before the hearing. Also, please bring 75 copies of your statement with you to the hearing.

The typed statement should be single-spaced, if possible. If your prepared statement will require more than 10 minutes of oral testimony, please be prepared to summarize it in approximately that time. Your entire statement will be printed in the hearing record.

I greatly appreciate your cooperation in this matter and look forward to your testimony. If you have questions, please contact Bill Layden at 202/225-2548.

Sincerely,

A handwritten signature in black ink, appearing to read "Towns", written over a horizontal line.

Edolphus Towns
Chairman

Subcommittee on Human Resources
and Intergovernmental Relations

ET:bl

JOHN CONYER JR. MICHIGAN
CHAIRMAN

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Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

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WASHINGTON, DC 20515-8143

November 8, 1993

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ROB PORTMAN OHIO

BERNARD SANDERS VERMONT
INDEPENDENT

MAJORITY—(202) 225-5081
MINORITY—(202) 225-5074

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Secretary Espy:

As you are aware, the Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations, held a hearing on November 4, 1993, to receive testimony from a variety of consumer and expert witnesses on the extent of progress the U.S. Department of Agriculture (USDA) is making to reform meat and poultry inspection. The hearing revealed dangerous flaws in USDA's inspection programs. In particular, witnesses provided alarming and disconcerting information about USDA's continuing inability to ensure the safety of meat and poultry products.

As a result of the testimony received at this hearing, I believe it is imperative your Department testify before this subcommittee about the progress it is making to reform the meat and poultry inspection programs. I have scheduled a hearing on Friday, November 19, 1993, at 9:15 a.m., in room 2247 of the Rayburn House Office Building to receive your testimony. Specifically, I would like you to address the issues outlined in my letter of October 4, 1993.

In my October 4, 1993, letter I also requested, among other things, that your Department fully brief my staff, on or about October 15, 1993, on the status of and plans for all USDA initiatives to reform meat and poultry inspection programs. Specifically, I requested that you provide a brief description of these initiatives, the estimated level of effort needed to achieve the objective (e.g., staff years and resources), the projected time tables to completion, and results to date. While we appreciate the briefing and documents your staff provided to the subcommittee staff on October 15, 1993, neither the briefing nor the documents provided were fully responsive to my request for information.

I am again requesting that you provide to the subcommittee the following information in writing by Monday, November 15, 1993: a brief description of all USDA initiatives to reform the meat and poultry inspection programs, the estimated level of effort needed to achieve the objective (e.g., staff years and resources), the projected time tables to

Secretary Espy
November 8, 1993
Page Two

completion, and results to date. If you cannot provide this information in the form requested by that date, please provide the subcommittee with a written explanation of why the information cannot be provided by that date and when it can be provided.

At this time, I also request that you provide to the subcommittee the following documents by November 15, 1993: (1) all news releases, "backgrounders," fact sheets, or other public affair documents issued or released by USDA from December 1992 through the present time concerning E. coli 0157:H7 and/or USDA's initiatives to reform meat and poultry inspection; and (2) all records written or received by agency employees--including, but not necessarily limited to, notes, memoranda, correspondence, electronically transmitted communications, and other drafts, analyses or reports--in any way related to USDA's policy and procedures on "zero tolerance."

I would like to stress the importance of complying with the subcommittee's document requests by November 15. Unless the subcommittee reviews these documents in a timely fashion, we will not be able to evaluate fairly the Department's progress towards implementing your initiatives before the hearing. This would not be in the best interest of USDA or the American public.

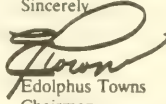
Please arrange to have 50 copies of your prepared statement delivered to the subcommittee at room B-372 Rayburn House Office Building, Washington, D.C. 20515-6148, by 5:00 p.m., on November 17, 1993. Such advance submission is required in order to give the Members an opportunity to study your statement before the hearing. Please bring an additional 100 copies of your statement with you to the hearing for public distribution. The typed statement should be single-spaced with two-sided copying, if possible.

You will have 10 minutes to present oral testimony. If your prepared statement will require more than 10 minutes of oral testimony, please be prepared to summarize it in approximately that time. Your entire written statement will be printed in the hearing record. There will be a question and answer period with the Members at the end of your statement.

Secretary Espy
November 8, 1993
Page Three

I greatly appreciate your cooperation in this matter and look forward to your testimony. If you have questions, please contact Bill Layden at 202/225-2548.

Sincerely

A handwritten signature in black ink, appearing to read "Towns", with a stylized flourish at the end.

Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

ET:bl

cc: The Honorable Steven Schiff
(Ranking Minority Member)

JOHN CONYERS JR. MICHIGAN
CHAIRMAN

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Congress of the United States

House of Representatives

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BOB PORTMAN OHIO

BERNARD SANDERS VERMONT
INDEPENDENT

MAJORITY—(203) 228-6061
MINORITY—(202) 228-6074

November 24, 1993

MEMORANDUM

TO: Members of the Subcommittee on Human Resources and Intergovernmental Relations

FROM: Edolphus Towns, Chairman

RE: USDA Commitment To Comply With The Subcommittee's Information Requests By December 17, 1993

Eugene Branstool, Assistant Secretary, Marketing and Inspection Services, U.S. Department of Agriculture (USDA), today agreed to fulfill the subcommittee's information requests on or before **December 17, 1993** (see attached correspondence). USDA has also agreed to meet with subcommittee staff on or before December 17, 1993, to deliver the information and to resolve any open questions on the information provided. I will inform you of the exact date and time of the meeting as soon as we hear from USDA.

I hope that Mr. Branstool's pledge to cooperate fully with the subcommittee will alleviate the need for compulsory process to obtain the requested information.

Attachments (3)



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

November 24, 1993

Honorable Edolphus Towns
Chairman
House Government Operations Subcommittee
on Human Resources and Intergovernmental
Relations
Rayburn House Office Building
Room 2157
Washington, D.C. 20515-6143

Dear Mr. Chairman:

I am writing in response to your November 23, 1993 letter to Secretary Espy which outlined the Subcommittee's request and granted an extension of time as per mutually agreed by our staffs on November 21, 1993.

I feel confident that we will fulfill the Subcommittee's request on or before December 17, 1993. Accordingly, I directed my staff to immediately compile the materials, information and data requested and to formulate the answers to the questions posed during the hearing as well as in your correspondence. As indicated in your letter, my staff will meet with your Subcommittee staff on or before December 17, 1993 to deliver this information to your staff as well as to resolve any open questions on the information provided.

I look forward to working with you and the Subcommittee on addressing these important issues. As I testified before your Subcommittee, both Secretary Espy and I are strongly committed to improvement of the meat and poultry inspection program.

Sincerely,

A handwritten signature in cursive script that reads "Eugene Branstool".

Eugene Branstool
Assistant Secretary
Marketing and Inspection Services

JOHN CONYERS JR. MICHIGAN
CHAIRMAN

CARLOS COLLINS KLINING
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House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

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November 23, 1993

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JOHN L. MICA FLORIDA
RON PORTMAN OHIO

BERNARD SANDERS VERMONT
INDEPENDENT

MAJORITY--(202) 225-8081
MINORITY--(202) 225-8074

Mike Espy
Secretary
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Secretary Espy:

As you are aware, the Subcommittee on Human Resources and Intergovernmental Relations, House Committee on Government Operations, held a hearing on November 19, 1993, to hear from the U.S. Department of Agriculture (USDA) about the progress it is making to reform meat and poultry inspection. At that hearing, several subcommittee members expressed serious concerns about USDA's failure to provide the subcommittee all the information we requested in our letters to you of October 4, and November 8, 1993 (see attachments I and II). Eugene Branstool, Assistant Secretary for Marketing and Inspection Services, who represented the Department, promised to finally provide this information to the subcommittee by close of business Monday, November 22, 1993.

In a letter to the subcommittee on Monday, November 22, 1993, Mr. Branstool requested an extension of time until December 17, 1993 to ensure that the Department would be able to respond fully to the subcommittee's requests for information. The subcommittee approves of this one-time extension with the understanding that the Department intends to provide all the information we have requested by December 17, 1993.

In order to avoid any misunderstanding, I would like to again state what information this subcommittee has requested and what information you have committed to provide to us by December 17, 1993:

- (1) You will provide complete written responses to the issues I had asked you to address at the November 19, 1993 hearing--specifically, questions 1, 2, 4, 5 and 6 and all sub-questions contained therein on pages one and two of my letter to you on October 4.
- (2) You will provide in writing a brief description of all USDA initiatives to reform meat and poultry inspection programs, the estimated level of effort

Secretary Espy
November 23, 1993
Page Two

needed to achieve the objective (e.g., staff years and resources), the projected time tables to completion, and results to date. For example, the subcommittee expects that you will provide information on all activities associated with the Department's Track I and II initiatives as well as the Pathogen Reduction Program.

- (3) You will provide more complete, detailed and understandable information on the status of all USDA initiatives to reform meat and poultry inspection programs than was provided in both the Department's November 16 and 18 draft status charts on the Pathogen Reduction Program (attachments III and IV). As requested in number 2 above, for each initiative, sub-initiative, task, project, step, etc., please provide (a) a brief description of the initiative, especially the measurable objectives or goals of each; (b) the estimated level of effort needed to achieve the objective of the initiative or task (e.g., staff years and resources); (c) the projected time tables to completion; and (d) all results to date.

For example, on page 2 of your November 18, 1993 draft chart under "Develop rapid methods," the subcommittee expects that you will provide more specific information on the measurable goals of this initiative, including all related tasks, such as "Develop and validate (number) rapid methods to detect (a pathogen) by (date) for use on (ground beef, etc.)." The subcommittee also expects that you will provide specific information on the amount of resources USDA is devoting to the initiative and each task, the projected time tables for completing each task and the overall initiative and all results to date.

- (4) You will provide a list of all initiatives to reform the meat and poultry inspection programs that have not yet been started or implemented.

Let me also convey my understanding of further agreements reached between our staffs during a meeting yesterday morning:

- (1) In those cases where you may be unable to provide precise data, such as with the level of effort or the amount of time needed to complete an initiative, you will provide the Department's best estimate and explain the basis of the estimate. In the event you are unable to provide precise data and a best estimate you will explain in writing to the subcommittee by December 17, 1993, why the Department is unable to provide the specific information requested by that date, when the information will be provided, or why the information cannot be provided.

Secretary Espy
November 23, 1993
Page Three

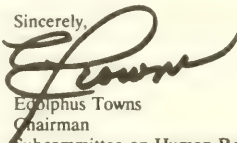
- (2) You will present the information requested in a meeting with the subcommittee staff on or before December 17, 1993, and resolve any open questions on the material provided before it is included in the hearing record of November 19, 1993.

Please confirm your concurrence of this understanding of the information you have promised to provide the subcommittee on December 17, 1993 in writing to the subcommittee by close of business, Wednesday, November 24, 1993.

Finally, I believe it is important to state to you that Mr. Branstool's characterization of the subcommittee's information request as "additional" and "supplemental" is wrong. USDA has failed to comply with the subcommittee's earlier requests for relevant information, necessary for the subcommittee to fulfill its oversight responsibilities pursuant to Rules X and XI of the U.S. House of Representatives.

I greatly appreciate Mr. Branstool's pledge to cooperate fully with the subcommittee in this matter. I hope through this cooperative relationship that the subcommittee can avoid the need for compulsory process to obtain the information you have promised to provide on December, 17, 1993. If you have any questions, please contact Bill Layden at 202/225-2548.

Sincerely,



Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

ET:bl

Attachments (4)

cc: The Honorable Steven Schiff
(Ranking Minority Member)



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

November 22, 1993

The Honorable Edolphus Towns
Chairman
Government Operations Committee
Subcommittee on Human Resources
and Intergovernmental Relations
Rayburn House Office Building

Dear Chairman Towns:

As a result of a meeting this morning between USDA staff and your staff, we are confirming that the additional and supplemental information that you have requested can be forwarded to your committee on December 17, 1993. Mr. Bill Layden of your committee staff has expressed to my staff that this extension of time would be amenable to you and the committee.

As always, I look forward to a strong working relationship with your committee. Confirmation of approval by letter of this extension of time would be greatly appreciated. If you have any questions, please feel free to contact Moe Vela or myself at 720-4256.

Sincerely,

A handwritten signature in dark ink, reading "Eugene Branstool", is written over the typed name.

Eugene Branstool
Assistant Secretary
Marketing and Inspection Services

JOHN CONYERS JR. MICHIGAN
GRAHAM

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GLEN E. GUNSH OF ALABAMA
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Congress of the United States

House of Representatives

COMMITTEE ON GOVERNMENT OPERATIONS

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ROB PORTMAN OHIO

BERNARD SANDERS VERMONT
INDEPENDENT

MAJORITY—(202) 226-5051
MINORITY—(202) 226-5074

DRAFT

November 16, 1993

MEMORANDUM

TO: Members of the Subcommittee on Human Resources and
Intergovernmental Relations

FROM: Edolphus Towns, Chairman

RE: Continuation of Hearing: "Reinventing the Federal Food Safety System:
USDA's Progress in Reforming Meat and Poultry Inspection," Friday,
November 19, 1993, at 9:15 a.m., 2247 RHOB

I. INTRODUCTION

On Thursday, November 4, 1993, the subcommittee heard testimony from several witnesses, including parents of E. coli 0157:H7 victims, on the lack of progress the U.S. Department of Agriculture (USDA) is making to reform meat and poultry inspection. Several witnesses also testified on the need to transfer meat and poultry inspection functions to a "public health" agency because of the perceived conflict in USDA's dual mission: agriculture production and consumer protection. (See written statements of witnesses and my memorandum of November 1, 1993.)

II. OBJECTIVES OF THE HEARING

This hearing is a continuation of the November 4, 1993 hearing to hear testimony from USDA on

- (1) what progress it is making in reforming meat and poultry inspection, and
- (2) whether meat and poultry inspection responsibilities should be transferred from USDA to an agency with a more "public health" mission.

The USDA hearings are the first in a series of hearings on the need to revamp the federal food safety system. Subsequent hearings will focus on FDA's role and options for reinvention.

III. WITNESSES

Eugene Branstool, Assistant Secretary, Marketing and Inspection Services, and other USDA staff will testify on November 19. We have not invited any other witnesses. We expect that the USDA staff supporting Mr. Branstool will include Ms. Pat Jensen, Deputy Assistant Secretary, Marketing and Inspection Services, and Dr. Russell Cross, Administrator, Food Safety and Inspection Service.

VI. MAJOR ISSUES

A. SAFETY OF MEAT AND POULTRY AND ADEQUACY OF USDA'S INSPECTION PROGRAMS

In two letters to the Secretary, USDA, on October 4, 1993 and on November 8, 1993, we asked USDA to address the following issues:

- (1) What are the primary risks to public health associated with meat and poultry? Do these risks differ significantly from those posed by other food products, such as buffalo meat, shellfish, or low-acid canned food? If so, how? What rationale exists, other than an historical one, to justify differences in the approach and intensity of the federal government's inspection and regulation of different food products and commodities?
- (2) To what extent is the present meat and poultry inspection system designed to prevent, control, reduce, or eliminate the primary risks to public health associated with meat and poultry products? What are the gaps and limitations in the present system's ability to manage these risks? To what extent is the present system designed to control animal diseases and economic adulteration?
- (3) What is the status of USDA's efforts to reform and modernize the meat and poultry inspection system?
- (4) What more needs to be done to further reduce and prevent the risks to public health from meat and poultry products?
- (5) What would an optimal federal food safety system look like? What should be the major components and guiding principles of an optimal system?

What options exist for developing and implementing such a system?

- (6) Should the federal government revamp its food safety system and, if so, how?

B. STATUS OF USDA'S REFORM INITIATIVES

On November 8, 1993, we again asked Secretary Espy to provide the following information in writing by Monday, November 15, 1993: a brief description of all USDA initiatives to reform the meat and poultry inspection programs, the estimated level of effort needed to achieve the objective (e.g., staff years and resources), the projected time tables to completion, and results to date. On Tuesday, November 16, 1993, Dr. Jill Hollingsworth, Assistant to the Administrator, FSIS, Ms. Linda Swacina, Deputy Director, Legislative Affairs, FSIS, and Ray Callstrom, Acting Assistant Deputy Administrator, Inspection Operations, FSIS, met with subcommittee staff and discussed the attached draft status report of the pathogen reduction program initiatives (the centerpiece of Secretary Espy's initiatives).

The status report indicates that USDA has "completed" or "accomplished" many specific components and elements of the initiatives that Secretary Espy and staff presented in testimony on February 5, 1993 before a subcommittee of the Senate Agriculture Committee.¹ According to Dr. Hollingsworth, USDA, in fact, has made a tremendous amount of progress in developing and integrating the pathogen reduction program into USDA's everyday business. She added that in the 8 months that have elapsed since the February hearing the Department has expended a tremendous amount of effort to "complete" these initiatives and many more have been "initiated."

During the staff briefing it became clear that many of the activities and projects that USDA considers "complete" or "accomplished" represent USDA's determination that the work needed to implement the initiative has been "completed," but that the activity itself is on-going or incomplete. This is especially true for research projects where there are no fixed end points. Dr. Hollingsworth noted that many of the initiatives are not discrete projects with finite end points, but rather represent the implementation of new programs that will continue indefinitely or new research projects the end point of which will be determined by the research yet to be conducted.

Dr. Hollingsworth declined to quantify USDA's progress in terms of the number of initiatives completed or initiated because she thinks that the reform efforts have so evolved since the February hearing that the efforts are now part of daily business and

¹U.S. Senate, "Food Safety and Government Regulation of Coliform Bacteria," Hearing before the Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation, Committee on Agriculture, Feb. 5, 1993.

not discrete projects. She added that the numbers she used during the February hearing were rough approximations that she developed during the course of the testimony. She believes that the Department has exceeded the progress that she estimated because she believes that many more than 14 initiatives have been "completed"--implemented.

Time has not permitted subcommittee staff to analyze fully the draft status report provided and several data points remain incomplete. USDA staff promised to provide further information as part of the Department's written statement expected on November 17, 1993.

C. VICE PRESIDENT'S RECOMMENDATION

See my memorandum of November 1, 1993, for more information on this issue.

Attachments

DRAFT

PATHOGEN REDUCTION PROGRAM INITIATIVES

INITIATIVE	DESCRIPTION	STATUS
LIVE ANIMAL ACTIVITIES		
Conduct comprehensive research	Determine the source and incidence of E. coli O157:H7 and other pathogens.	<ul style="list-style-type: none"> - APHIS has lead. - FSIS personnel detailed to project. All data collection for E. coli research project in Ft. Collins will be collected by December 1993. Results to be available in early 1994.
	Conduct epidemiological field studies for risk analysis, control, and intervention strategies.	Ongoing for E. coli. Future data collection will address additional commodities and pathogens.
	Collect baseline data on pathogen presence and monitor for trends, geographic differences and causal links.	APHIS has begun long-term planning with CDC, FDA, FSIS. Investigation protocols being developed for future and respective roles being identified. APHIS continues involvement in traceback investigations of food-borne illnesses.
Conduct on-farm investigations	Conduct targeted on-farm investigations to confirm current assumptions about sources and good preventive measures that can be quickly implemented.	
Develop rapid methods	Develop rapid tests and other methods necessary to identify pathogens at the critical points in live animals.	
Establish methods for the identification and traceback of animals	To facilitate on-farm prevention programs and permit better investigation of the source of E. coli O157:H7.	<ul style="list-style-type: none"> - Initiated - Legislative authority needed. - Legislative package including id/traceback under administrative clearance.
Develop on-farm pathogen prevention program/models	Support research for pathogen prevention, including development of vaccines.	<ul style="list-style-type: none"> - Completed and ongoing - FSIS funded research on vaccine development at University of Georgia. - FSIS is analyzing research findings and international experience to develop models.

Source: LINDA SWACINA, Deputy Director, Office of Legislative Affairs, FSIS, USDA, 720-3897

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	Integrate and analyze data on pathogens from State, universities, veterinary diagnostic laboratories, and FSIS data base.	APHIS has begun identifying research needs with ARS: Results of this, other research, and ongoing APHIS studies should lead to prevention models before 1995. Workshops in strategies for managing preharvest food safety are planned for 1994.
	Work with producers to introduce voluntary, industry-supported herd certification program.	
SLAUGHTER PLANT ACTIVITIES		
Expand microbiological baseline program	Immediately add cows to national microbiological baseline monitoring.	- Completed. - Cow-bull monitoring initiated 8/93. - Monitoring is ongoing.
	Also expand to poultry and swine.	- Initiated. - Poultry and pork study concept papers distributed to scientific reviewers. Studies will begin in 1994.
	Encourage plants to collect microbiological data.	- Completed. - Accomplished through speeches, meetings, conventions, etc.
	Use data to establish targets for reducing pathogens.	- Initiated.
	Conduct steer/heifer survey.	- Completed 9/93. - Report to be issued 12/93. - Additional monitoring of steers/heifers ongoing.
Evaluate current slaughter and processing methods. Assure they are adequate to reduce carcass contamination and prevent temperature abuse and other potential causes of bacteria proliferation	Reinforce mandatory trimming of all fecal and milk contamination in slaughter operations.	- Completed. - Memos to inspectors sent 2/1 and 3/2/93. - AQL changed.
	Implement a stronger pre-operational sanitation inspection program in meat slaughter plants.	- Initiated. - Plan completed. - Union negotiations completed. - Training underway.
	Begin pre-op sanitation micro-monitoring study for poultry.	- Initiated. - Plan/Protocol completed - Pilot testing underway - Study to begin 1/94.
	Revise Sanitation Handbook issued to all inspectors.	- Revisions underway. - Completed Handbook expected in early 1994.

Develop rapid methods	Develop rapid tests and other methods necessary to identify pathogens at the critical points.	<ul style="list-style-type: none"> - Initiated. - FSIS published FR announcement on 8/12 stating criteria for rapid test needs.
Use organic acid and other prevention systems	Encourage use of organic acid sprays or other prevention systems to reduce pathogens on surfaces of beef carcasses. If voluntary use is inadequate, mandate use.	<ul style="list-style-type: none"> - Completed. - Mandatory use not supportable at this time. - TSP use expanded to turkeys. - Testing on beef hide dehairing.
Critical Control Point (CCP) Microbiological Verification Testing	Monitor for CCP's in beef slaughter plants for total coliforms, E. coli and Aerobic plate count to determine adequacy of plant's process control.	<ul style="list-style-type: none"> - Initiated. - Testing begun 11/93.
Study on beef carcass washing v. trimming	Develop protocol for scientific review approval	- Completed.
	Study to determine which is more effective in removing fecal contamination.	- 1-year study scheduled to begin in 11/94.
Test "disabled" and other "suspect" animals	Test disabled animals to determine if pathogens are more prevalent.	<ul style="list-style-type: none"> - Initiated. - Study begun 9/93.
Enhance veterinary coverage of higher risk slaughter plants	Evaluate veterinary staffing in higher risk slaughter plants to ensure that public health expertise is proportional to the risk.	<ul style="list-style-type: none"> - Completed. - Veterinarian reassignments made and ongoing as other problems plants identified.
Mandate records	Issue regulations to strengthen requirements that slaughter plants maintain complete and accurate records of all their transactions (purchases and sales). Focus on records that facilitate traceback and control measures.	<ul style="list-style-type: none"> - Initiated. - Regulations under review. - Publication target is January 1994.
Tighten enforcement through unannounced reviews of slaughter plants	Conduct unannounced reviews of meat plants to determine effectiveness of inspection.	<ul style="list-style-type: none"> - Completed and ongoing. - Several plants shut down from a few hours to a few days to correct deficiencies.
Control bacteria in trimmings	Establish and enforce strict time and temperature requirements to reduce bacteria proliferation in meat trimmings. Include steps to monitor storage and transportation. Restrict use of incoming products that exceed established temperatures.	<ul style="list-style-type: none"> - Initiated. - Review of procedures and development of possible approaches underway. - Analyzing existing data to establish scientific basis.
Finalize "patties" regulation	Issue final regulation for cooking and handling of patties produced at federally inspected establishments. Mandate handling instructions for partially cooked products.	<ul style="list-style-type: none"> - Completed. - Final regulation published 8/93.

	<p>Pending the effective date of the final rule, issue instructions to field inspectors to encourage voluntary compliance and report any significant deviations immediately.</p> <p>Also issue regulations for other ready-to-eat beef products.</p>	<ul style="list-style-type: none"> - Completed. - Inspectors issued special thermometers for monitoring internal patty temperature. - Instructions for monitoring/use of thermometers provided. - Initiated. - Rule drafted. - Impact analysis underway.
Mandate safe handling labels	Mandate safe handling instructions for labels on all raw meat and poultry products.	<ul style="list-style-type: none"> - Completed. - Proposed regulation published 11/93.
Test raw ground beef	Test raw ground beef patties for total coliforms, E. coli and Aerobic Plate Count.	<ul style="list-style-type: none"> - Initiated. - Testing began 11/93.
Research irradiation	Give immediate priority to research to support a petition for FDA approval of irradiation for fresh ground beef and beef trimmings.	<ul style="list-style-type: none"> - Completed. - Outside research concluded. - Proposal to fund petition forwarded for Department decision.
Evaluate inspection in processing plants	Use potential public health risk to make staffing and inspection task adjustments in processing plants.	- Completed and ongoing as part of PBIS.
	** Update Sanitation Handbook issued to all inspectors.	<ul style="list-style-type: none"> - Initiated. - Revisions underway. - Completed Handbook expected in 1994.
	**Repeat of slaughter plant entry.	
Recordkeeping requirements	<p>** Assure that processing plants maintain complete and accurate records of all their transactions (purchases, formulations, and sales). Focus on records that aid in identification and traceback.</p> <p>** Repeat of live animal entry.</p>	<ul style="list-style-type: none"> - Initiated. - Legislative authority needed. - Legislative package including id/traceback under administrative clearance.
FOOD SERVICE STEP ACTIVITIES		
Sponsor teleconference	Invite the Department of Health and Human Services to join with USDA in sponsoring a teleconference for State and local public health authorities to share information on such subjects as food safety requirements and their enforcement.	<ul style="list-style-type: none"> - Completed. - Teleconference held 9/1. - Other teleconferences may be held due to favorable participant reaction.
Help State enforcement programs	Using the teleconference as the first step, actively lead a major initiative to cooperate with States to provide emergency and ongoing Federal assistance and advice. Stress the need for better enforcement of safety standards in retail stores and restaurants.	<ul style="list-style-type: none"> - On-going. - In response to requests from States, FSIS is developing a video on how to test meat and poultry.

Educate food handlers	Use the targeted education program for food service employees, day care centers, nursing homes and similar institutions to stress proper cooking and handling.	<ul style="list-style-type: none"> - Completed and will be ongoing. - FNS distributing food safety information through the FNS Child Care Food Program. - FSIS is preparing a video of food safety for use in training programs for child care supporters.
Educate fast food restaurant employees	Call upon corporate leaders of fast food "chains" and other restaurants to educate their food service employees and follow up to ensure that information is understood and applied correctly.	<ul style="list-style-type: none"> - Completed.
Label school lunch products	Require "safe handling" inserts and prominent cooking labels on all school lunch products.	<ul style="list-style-type: none"> - Completed. - FNS also sending notices to facilities that obtain USDA-purchased foods to provide posters and other information about safe handling.
	Send notices to School Food Service Directors to alert them to concerns about thorough cooking.	
	Consider a similar campaign for other Federal facilities (military, Veterans hospitals, etc.)	
Enhance model codes	Work with FDA and the States to assure adequate controls in the model retail code.	<ul style="list-style-type: none"> - Completed. - Model Code announcement pending.
CONSUMER AWARENESS STEP ACTIVITIES		
Enhance consumer awareness campaign	Develop a national consumer awareness campaign to stress improved public understanding of the risks of unsafe food handling practices. Prepare specialized materials for the campaign, such as columns for small newspapers, information for magazine articles, video news releases and media packages.	<ul style="list-style-type: none"> - Completed and ongoing.
Promote materials	Promote existing and new consumer education materials. Work with "information multipliers," such as State Extension agents, industry groups, academic institutions and consumer and health groups to maximize distribution.	<ul style="list-style-type: none"> - Completed and ongoing.
Expand food safety education	Increase cooperative efforts with other agencies and organizations who share roles as food safety educators.	<ul style="list-style-type: none"> - Completed and ongoing.

FEDERAL GOVERNMENT PROCESS		
Improve Inspection -- USDA will improve its meat inspection program to respond to the known microbial risks to the public health. Food inspectors and veterinarians will be trained and provided with the technology, such as diagnostic tools and information systems, needed for modern inspection.	Hire 200 new inspectors.	- Completed.
	FSIS HACCP training team selected to identify training needs, resource requirements, etc.	- Initiated.
	Implement training of inspectors to conduct micro monitoring.	- Completed.
	Develop HACCP education program	- Initiated.
USDA Pathogen Reduction Task Force	An interagency task force will be formed to address other needs - research, regulatory, etc. - that will aid in future prevention activities.	- Initiated.
Reorganize FSIS HQ	Reorganize FSIS Headquarters to ensure future inspection needs are met.	- Initiated. - Reorganization proposal submitted for approval.
	Establish new division for ongoing Special Reviews.	- Completed. - FSIS Office of Review and Assessment established.
	Establish FSIS position at CDC for better coordination between Agencies.	- Completed. - Interviews of candidates underway.
	Form public health division within FSIS.	- Completed. - Consultations underway with Office of the Surgeon General and Public Health Service for candidates to head division.
Expand research authorities within USDA	Publish regulation permitting Agencies other than ARS to contract for research.	- Completed. - Regulation permitting FSIS to contract for or conduct research published 8/12/93.

PATHOGEN REDUCTION
(Dollars in thousands)

ACTIVITY	FY 1994
I. PRE-HARVEST PRODUCTION ACTIVITIES	250
A. On-farm investigations	100
B. Animal ID and traceback	150
C. Develop pathogen prevention programs	0
II. DEVELOP RAPID METHODS	1,000
A. Methods development research	1,000
B. Center of Excellence - UMES	0
III. POST-HARVEST ACTIVITIES	1,150
A. Conduct slaughter and processing research	1,000
B. Irradiation Petition	150
IV. QUANTITATIVE RISK ASSESSMENT	150
A. Quantitative Risk Assessment	150
V. SLAUGHTER PLANT ACTIVITIES	4,000
A. Expand microbiological baseline	2,500
B. Test disabled cows	0
C. Improve current slaughter procedures	0
D. Enhance veterinary coverage	0
E. Mandate record-keeping	0
F. HACCP micro monitoring	1,500
G. Inspector Training	0
VI. PROCESSING PLANT ACTIVITIES	1,000
A. Control bacterial proliferation	0
B. Improve current processing procedures	0
C. Finalize "patty" docket & controls on similar products	0
D. Mandate safe-handling labels	0
E. HACCP micro monitoring	1,000
F. Inspector Training	0
VII. COORDINATION AND EDUCATION ACTIVITIES	300
A. Sponsor teleconference	0
B. Assist State enforcement programs	0
C. Educate food handlers	200
D. Educate fast food chain employees	100
VIII. CONSUMER AWARENESS ACTIVITIES	150
A. Intensify consumer awareness campaign	0
B. Expand food safety education	150

56,24

BREAKDOWN OF THE \$8,000,000 FOR PATHOGEN REDUCTION

PRE-HARVEST PRODUCTION ACTIVITIES	\$250,000
On Farm Investigations	\$100,000
Animal ID and traceback	\$150,000
DEVELOP RAPID METHODS	\$1,000,000
Methods Development research	
POST HARVEST ACTIVITIES	\$1,000,000
Slaughter and processing research	
RISK ANALYSIS	\$150,000
Quantitative risk analysis	
SLAUGHTER PLANT ACTIVITIES	\$4,000,000
Expand the microbiological baseline	\$2,500,000
HACCP micro monitoring	\$1,500,000
PROCESSING PLANT ACTIVITIES	\$1,000,000
HACCP micro monitoring	
FOOD SERVICE AND RETAIL ESTABLISHMENTS	\$300,000
Educate food handlers	\$200,000
Educate fast food chain employees	\$100,000
CONSUMER AWARENESS	\$300,000
Intensify Consumer Awareness Campaign	\$150,000
Expand food safety education	\$150,000
TOTAL.....	\$8,000,000



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D. C. 20250

Honorable Edolphus Towns
Chairman
House Committee on Government Operations
Subcommittee on Human Resources and
Intergovernmental Relations
2157 Rayburn House Office Building
Washington, D. C. 20515

Dear Mr. Chairman:

I am forwarding to you additional information on the U. S. Department of Agriculture's programs and policies as a follow up to your subcommittee hearings on November 4 and 19, and to respond to the request of your correspondence.

Specifically, in your letter to Secretary Espy dated October 4, 1993, you asked six questions concerning meat and poultry inspection. The answer to each of these questions is attached.

I hope this information will be helpful to you and the Members of your subcommittee. If you have any additional questions, please let me know and I will respond to your request.

Sincerely,

A handwritten signature in cursive script, reading "Eugene Branstool", followed by a diagonal line and the initials "EB".

Eugene Branstool
Assistant Secretary,
Marketing & Inspection Services

Subcommittee Note.--This information, which was received on December 17, 1993, is retained in the subcommittee's files. However, it was superceded by USDA's January 25, 1994, submission.



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DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250
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January 25, 1994

The Honorable Edolphus Towns
United States Congress
2232 Rayburn House Office Building
Washington, D.C. 20515-3210

Dear Congressman Towns:

Enclosed is an updated copy of Responses to Questions of October 4, 1993 and Appendix A for the December 17, 1993 document submitted by Assistant Secretary Gene Branstool to the Subcommittee on Human Resources and Intergovernmental Relations of the House of Representatives' Committee on Government Operations. I appreciate the opportunity to update these materials.

You will notice that Appendix A has been divided into Type of Activity and then subdivided by initiative. All activities pertaining to a particular initiative are easily discernable in this format. You will also notice that enclosed within Appendix A is a tab labeled "New Initiatives" consisting of two Activity Charts (charts A-47 and A-48) which were not included in the December 17 submission. These two charts reflect activities which I believe have been discussed with the Subcommittee subsequent to Assistant Secretary Branstool's initial submission of materials on November 19, 1993.

I trust you will find this substitute material satisfactory. If you need additional information, do not hesitate to call me or Martin Rookard of my staff.

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia Jensen".

Patricia Jensen
Acting Assistant Secretary
Marketing & Inspection Services

Responses to Questions of October 4, 1993

1. (a) What are the primary risks to public health associated with meat and poultry?

The primary risks to public health from all food sources, including meat and poultry, can be categorized as physical, chemical, and biological. Physical hazards can include such things as metal, glass or other unidentified ingredients. Chemical hazards can include residues of animal drugs, pesticides, or environmental contaminants. Biological hazards include those associated with both diseases and microbial pathogens.

The degree of risk to public health is attributable to the inherent nature of the food itself, the environment in which it is grown and processed, and the effectiveness of the controls used in its preparation, handling, and storage. It is partially based on these variables that it was determined that USDA's food safety initiatives must include each step of the production of food -- from farm to table.

Centers for Disease Control data for the period 1983-1987 reveal that among all foodborne illness outbreaks in which the etiology was determined, bacterial pathogens caused the largest number of outbreaks (66%); chemical agents caused 26%; parasites, 4%; and viruses, 5% of the outbreaks. The etiology was not determined in about 60% of all outbreaks. This data is found at tab B.

These findings were echoed in a 1985 report on the scientific basis of the meat and poultry inspection program that was commissioned by the Food Safety and Inspection Service (FSIS), when a National Academy of Sciences (NAS) committee identified biological agents and chemical agents as the principal threats to public health in meat and poultry. The committee's report stated that, among the biological agents, Salmonella and Campylobacter were among the most significant public health hazards. These bacteria are currently known to reside in the digestive tracts of healthy animals.

In addition, foodborne disease can be caused by organisms in meat and poultry that are located outside of the digestive tract. These diseases include toxoplasmosis, trichinosis, cysticercosis (caused by tapeworms), and botulism. Toxins from molds and other microorganisms, such as aflatoxin B₁, also have public health implications for the consumer of meat, poultry, and other products.

The sources of such contaminants can be production-related or processing-related and the contamination can result from the use

of agricultural chemicals or from exposure to chemicals in the environment. Examples of the use of chemicals that could lead to residues in meat and poultry (and other foods) are the application of pesticides and fertilizers to facilitate the growth of crops, including those used as animal feed. Sources of chemical residues in meat and poultry also include therapeutic and subtherapeutic uses of antibiotics and sulfonamides to control disease and promote growth in livestock and poultry.

Because FSIS has made substantial progress in controlling chemical residues, the primary risks currently associated with the consumption of meat and poultry products remain those arising from microbial pathogens associated with raw meat and poultry. The CDC has identified outbreaks of foodborne illness attributed to the consumption of chicken, pork, and beef products contaminated with Salmonella, Campylobacter, Listeria monocytogenes, or Escherichia coli.

In the CDC report found at tab B detailing foodborne disease outbreaks in the U.S. during a fifteen year period (1973-1987), the CDC reported the following:

- in 7,458 outbreaks involving 273,545 cases, Salmonella accounted for 42% of the outbreaks due to bacterial pathogens;
- the specific food causing an outbreak was identified in 50% of the outbreaks, (beef accounted for 9%, pork for 7%, and poultry for 7%);
- although beef remains a major vehicle for foodborne illness, the proportion of outbreaks and cases associated with beef decreased steadily over the 15- year period; and
- bacteria not previously recognized as important foodborne pathogens that emerged during the study period included Campylobacter jejuni, E. coli O157:H7, and Listeria monocytogenes.

(b) Do these risks differ significantly from those posed by other food products, such as buffalo meat, shellfish, or low-acid canned food? If so, how?

The risks associated with bison meat are essentially the same as those associated with beef.

The risks associated with the processing of canned meat and poultry products are essentially the same as those associated with other kinds of canned food, and the regulations enforced by FSIS with respect to canned, shelf-stable meat and poultry products are essentially the same as those enforced by FDA for

other types of canned, shelf-stable food.

The main hazards associated with shellfish are microbial pathogens and toxins. The types of organisms and substances of concern vary somewhat from those associated with meat and poultry products, but the health and safety concerns are similar in nature to those involving raw and processed meat and poultry.

Shellfish can acquire pathogenic microorganisms or toxins from the natural aquatic environment, from sewage-contaminated harvesting areas, and from contamination by workers, utensils, environmental conditions, and equipment during harvesting, processing, distribution, and food preparation. Even freshly caught fish and shellfish from unpolluted waters may contain pathogens such as Clostridium botulinum type E and Vibrio parahaemolyticus.

For many of the fish-borne and shellfish-borne diseases, faulty harvesting or postharvesting practices are the cause of outbreaks of disease. Included in this category are outbreaks caused by C. botulinum, V. parahaemolyticus, Staphylococcus aureus, hepatitis A, scombroid poisoning, Salmonella, Shigella, and Clostridium perfringens. In cases of botulism, staph poisonings, and clostridial infections, time-temperature abuse of the raw fish usually is involved. For V. parahaemolyticus infection, time-temperature abuse of raw-contaminated or post-heat-contaminated seafood is necessary. Salmonella, Shigella, and hepatitis A may enter seafood either from contaminated waters, from contaminated post-harvest procedures, or from contamination post-heating and cause disease in humans. Fish and shellfish that have ingested certain types of toxic dinoflagellates can be directly responsible for outbreaks of paralytic shellfish poisoning (PSP) and ciguatera. A General Accounting Office report on seafood safety and consumer protection provides additional information and can be found at tab D.

(c) What rationale exists, other than an historical one, to justify differences in the approach and intensity of the Federal Government's inspection and regulation of different food products and commodities?

An important rationale that justifies the differences in the approach and intensity of food inspection is the difference in risk between various food products. Meat and poultry products present a special risk for potential foodborne disease for a number of reasons. These include the following:

- Bacteria are part of the normal flora of meat and poultry animals. Some of these organisms can be pathogenic to

humans. This is usually not the case with non-animal food commodities such as fruits and vegetables which may be cross-contaminated with pathogenic organisms, but are not normally a natural host for bacteria.

- The chemical and physical make-up of meat and poultry is such that it supports the growth of bacteria and provides a medium in which certain organisms cannot only survive but rapidly multiply. This is not necessarily true with other food commodities.
- In determining the risk involved with any food, one consideration is the "sensitivity of the product." Sensitivity is determined by how well bacteria can survive in or on the product and whether there is a potential for microbiological abuse of the product in its production, distribution, or handling. Meat and poultry products under this definition must be considered sensitive products because they can naturally contain harmful bacteria and the potential for microbiological abuse is significant. The nature of the product is such that this kind of abuse could render the product harmful when ingested by humans.

Meat and poultry are tested by FSIS for pesticide residues based upon the potential for misuse or abuse of individual pesticides. The potential for a pesticide residue on a fruit or vegetable commodity is as great -- if not greater -- than a similar residue being found in a meat or poultry product. Consequently, the intensity of the Federal Government's inspection for pesticide residues can vary among food products based on risk to the public health.

Another important rationale for differences in the approach and intensity of inspection of different food products remains the historical rationale. The United States enacted its first inspection law in 1890, mainly to shore up confidence in U.S. products among buyers in foreign countries. In 1906, however, the concerns of domestic consumers were raised by Upton Sinclair's book, The Jungle. Although the book was intended to expose the poor treatment of workers in Chicago's packinghouses, it prompted public concern about unsanitary conditions in plants.

President Theodore Roosevelt ordered an investigation, and Congress enacted much stricter controls on meat production with The Meat Inspection Act of 1906. The Act required inspection of meat products sold in interstate and foreign commerce. Animals had to be inspected for disease at the time of slaughter, and processed products had to be inspected for harmful additives. Strict sanitation requirements for plants and truthful and accurate labeling requirements were established.

Animals and animal products have been placed under mandatory

inspection by Congress as consumption of the product has increased or public health concerns have arisen. For example, poultry was not included in the 1906 meat inspection law, since the industry was small and localized, and the sanitation problems that were recognized in the beef industry did not exist in the poultry industry at the time. In 1928, USDA established a voluntary poultry inspection program, and when poultry consumption began its explosive growth in the 1950's, Congress established a mandatory program under the 1957 Poultry Products Inspection Act. As consumption of seafood has increased, some consumers have raised concerns about potential food safety problems with seafood. As a result, legislation mandating seafood inspection has been introduced during several of the most recent sessions of Congress.

A copy of the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) are found at tab C. As you will note, the FMIA (Sec. 1 et seq.) specifically lists the species, and meat and products thereof, that must be federally inspected; the species are limited to cattle, sheep, swine, goats and equine. Bison and other food products are inspected on a voluntary basis by USDA, for a fee, under the Agricultural Marketing Act of 1946, as amended, (21 U.S.C. 1621 et seq.) They are also subject to periodic inspection by FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

2. To what extent is the present meat and poultry inspection system designed to prevent, control, reduce, or eliminate the primary risks to public health associated with meat and poultry products?

In the 1985 NAS report referred to in question one, the NAS committee identified biological and chemical agents as the principal threats to public health from meat and poultry. The report acknowledged that diseased animals also pose a threat to public health. FSIS' efforts have been effective in controlling diseased animal threats.

Under the current inspection program, FSIS is capable of detecting and identifying visible signs of disease or other abnormalities in livestock and poultry. In fact, since Secretary Espy has taken office, 200 new inspector positions have been created and a total of 400 new inspectors have been hired to assure better inspection. Such invisible hazards as contamination by biological and chemical agents, on which the NAS focused in its 1985 report, escape direct detection by traditional organoleptic inspection. By assuring that slaughter and dressing are carried out under sanitary conditions and procedures, the contamination of raw product with pathogens can be minimized, but other measures have been taken to further detect biological and chemical agents.

With respect to chemical agents, FSIS, through the National Residue Program (NRP), supplements traditional visual inspection which cannot detect chemical residues. The NAS committee recognized that FSIS was operating a monitoring and surveillance program that met most of the objectives of what they considered an optimal residue control program. Since the publication of the NAS report, FSIS has improved its residue control program in many ways, including adoption of most of the NAS recommendations.

Under the NRP, FSIS carries out scientific sampling and laboratory analysis. Rapid in-plant tests are provided to USDA inspectors for use in the monitoring phase of the NRP. Copies of the most recent NRP and testing results are found in the blue and red booklets found at tab E.

The inspection program has made progress in detecting illegal concentrations of drug and chemical residues in the meat and poultry supply. Information on such violations has been brought to the attention of other Federal agencies, such as FDA -- which participates with FSIS in the automated Residue Violation Information System (RVIS) -- and to producers. Through a coordinated effort involving monitoring of the Nation's livestock and poultry population, surveillance of segments of that population where problems may exist, and producer education, the

level of violative residues in meat and poultry samples has been substantially reduced. Overall violative residue levels for livestock have been brought down from above 5 percent in 1978 to .33 percent in 1992. For poultry, overall violative residue levels dropped from approximately 1 percent to 0.13 percent during the same period.

For products that have undergone certain types of processing, such as heat treatment that are intended to kill bacteria, there should be no pathogens. Thus, in a canned product, there should be no spore-forming anaerobic bacteria. In an irradiated chicken, there should be no viable salmonellae. In a fully cooked ham, there should be no live trichinae. Ready-to-eat products found to contain pathogens are considered adulterated. Where problems affecting processed products are known or suspected, USDA conducts surveys, collects samples, and uses laboratory methods to determine the nature and scope of the problems. Enforcement of inspection regulations mandating such things as time and temperature requirements for cooked products and steps to prevent recontamination and microbial surveillance programs have been effective in these types of ready-to-eat products.

(b) What are the gaps and limitations in the present system's ability to manage these risks?

We have been able to respond to the public health threat from chemical residues by making the sampling and testing plans for residues a part of the traditional inspection program. A complex, scientific dilemma exists with respect to biological agents. Although we are continually studying testing methods for usefulness and applicability to our programs, the technology doesn't provide us with adequate microbiological testing methods for our in-plant inspection program of raw meat and poultry in the same manner as it does for residue tests.

The current inspection program cannot rapidly detect foodborne pathogens in raw meat and poultry at the point of slaughter or processing. Samples must be collected and forwarded to a laboratory where they are cultured for analysis. Because organoleptic detection of these pathogens at the slaughterhouse is also not possible, we must rely, in part, on consumer awareness of the hazards and methods of preventing food poisoning. To this end, we have conducted food safety education programs. Consumers must be aware of safe methods of handling, storing, and cooking food. It is important to note that proper cooking will destroy pathogens of public health concern; proper handling minimizes the potential transfer to other foods. For this reason, Secretary Espy has aggressively sought to mandate the use of safe food-handling labels for meat and poultry products. A proposed regulation to mandate safe food-handling

labels on meat and poultry products has been published. It is found at tab Z.

The Department is pursuing the authority to mandate poultry and livestock traceback capability for the purpose of identifying the farm, feedlot, and other premises where animals were held prior to being presented for slaughter. Records kept for traceback purposes would create a system of data to be used in epidemiological studies that could show which poultry and livestock have a higher probability of carrying pathogens.

(c) To what extent is the present system designed to control animal disease and economic product adulteration?

Visual ante-mortem and post-mortem inspection, supported by laboratory science, is an invaluable tool for the detection of animal diseases, including zoonoses -- diseases that can affect both animals and humans. In 1992, FSIS inspectors condemned over 400,000 head of livestock and in excess of 72 million poultry carcasses. Under current statutes, all livestock undergo both ante-mortem and post-mortem inspection. Ante-mortem inspection is essential to the detection of diseases or conditions that may be difficult to detect on post-mortem, or for which post-mortem detection would be too late. For example, animals affected by rabies and listeriosis exhibit distinct behaviors on ante-mortem and are immediately condemned for human food purposes. Similarly, animals affected by anthrax, which is deadly to both humans and animals, can be prevented from entering the slaughterhouse, where they would pose a threat to slaughterhouse workers, inspectors, and veterinarians.

Post-mortem organoleptic inspection is very useful in the detection of a wide variety of animal disease conditions, such as those mentioned in the response to the question on public health risks, and those associated with such exotic and domestic animal diseases as African swine fever, hog cholera, contagious bovine pleuropneumonia, and bovine tuberculosis. Some animal diseases, such as brucellosis and tuberculosis, are transmissible to humans. FSIS also cooperates with its sister agency, the Animal and Plant Health Inspection Service (APHIS), in efforts to control animal diseases that pose a threat to our Nation's livestock and poultry populations. When certain diseases are detected on ante-mortem or post-mortem inspection, they are reported to APHIS's Veterinary Services. These include anthrax, avian influenza, exotic Newcastle disease, bluetongue, cysticercosis, scabies, tuberculosis, contagious ecthyma, myiasis (screwworm), scrapie, and vesicular diseases. Of these diseases, anthrax, cysticercosis, and tuberculosis are transmissible to humans (tuberculosis through unpasteurized dairy products).

Certain diseases that are detectable on post-mortem inspection are classified as emergency diseases whose reporting is an urgent necessity. These include foot and mouth disease, rinderpest, African swine fever, hog cholera, contagious bovine pleuropneumonia, and Teschen's disease.

FSIS participates in APHIS programs aimed at eradicating certain diseases. For example, FSIS collects livestock blood samples at slaughter for use in the brucellosis eradication program. Brucellosis is an incurable occupational disease that in the past was known to afflict slaughterhouse workers and food inspectors. FSIS also participates in the APHIS Slaughter Surveillance Program for bovine tuberculosis. Because of these efforts, there are now 32 brucellosis-free states, or 64% of all states, plus Puerto Rico, the Virgin Islands, and the District of Columbia are brucellosis-free.

In the area of economic product adulteration, the current inspection program includes numerous procedures intended to assure that consumers get what they pay for. Products are inspected for correct labeling, proper weight and quantity, composition, and ingredients. Products are subject to food chemistry tests for protein, moisture, fat, and salt content. Visual inspections and immunoassay procedures (rapid, in-plant tests) are applied to determine whether the species indicated on the label of a product is the species the product is actually made of. FSIS also checks to make sure that a product that is assumed to originate in a certain place really does so originate or that a product ostensibly processed according to a religious ritual really was so processed. For example, a product that is labeled "kosher" must be. It should be noted here that most -- if not all -- of the economic adulteration activities FSIS carries out are mandated by statute.

When the meat inspection program was first established, its objectives were to detect and condemn meat affected by diseases or other conditions that could be harmful to the consumer and to protect the consumer from meat that, while not harmful in the biomedical sense, was aesthetically repellant. Among the disease conditions and lesions considered most dangerous to the consumer at the time were septicemia, pyemia, tuberculosis, gangrene, peritonitis, enteritis, metritis, pneumonia, tumors, and abscesses. The detection of such conditions, which can occur in warm-blooded animals, is still part of the inspection program. The methodology used to detect these conditions is organoleptic, that is, it relies on use of the human senses.

At the inception of the inspection program, this method was considered to be the most efficient and effective way to detect meat and poultry that was a public health risk, or objectionable to the consumer. In many situations, it is still an important method to assure that meat with such conditions -- which render

it unwholesome and unfit for human consumption -- is found and removed before it can enter the food supply.

The intensity of slaughter inspection -- carcass by carcass -- is dictated by statute (Section 6 of PPIA and Sections 3 and 4 of FMIA). There will continue to be circumstances where continuous inspection will be justifiable in a risk-based inspection system. For example, in situations where large numbers of older animals or herds and flocks are known to have been exposed to disease are slaughtered, examination of individual carcasses by trained inspectors may be the most efficient and effective means of protecting the public health. In addition, the visual inspection of equipment and facilities is still a useful way to ensure that the environment in which slaughter and further processing are carried out is clean.

In summary, FSIS is aggressively pursuing a modernized inspection system which incorporates the best elements of organoleptic and scientific methods. FSIS is vigorously encouraging scientific research to help in its efforts. For example, infectious doses for pathogens are unknown, making realistic regulatory safety standards difficult to set; the scientific capability to detect pathogens quickly and safely in an in-plant environment does not yet exist; and animal husbandry, slaughter and processing technologies cannot yet produce raw products free of pathogens. However, we remain optimistic that science will lead the way with new research and discoveries.

In the meantime, FSIS can reduce pathogen levels by more vigilant inspection to reduce visible contamination on products, by incorporating microbial monitoring into plant sanitation inspections, and by intensified regulatory actions where necessary. FSIS is also intensifying our consumer education efforts.

The meat and poultry inspection system has evolved to include such diverse capabilities and functions as rapid tests and residue control programs to deal with residues and economic adulterants; compliance to deal with intentional violations of meat and poultry laws and regulations, more efficient in-plant inspection systems to ensure that available resources are used most effectively, review and assessment capabilities to better deal with inspection problems, and consumer education programs. The inspection system must evolve again to deal with pathogens on raw product. Secretary Espy's pathogen reduction program is at the forefront of this change.

3. **What is the status of USDA's efforts to reform and modernize the meat and poultry inspection system?**

Since taking office in January, Secretary Espy has moved aggressively to reinvent and rethink every aspect of meat inspection. For example, he has met with whistleblowers, consumer groups, industry and the families of those affected by the E. coli outbreak in the Northwest. He knows we need to make changes and he wants to get input from those who have felt left out in the past.

Secretary Espy has created 200 new inspector positions and moved into high gear a strategic pathogen reduction program that aims to prevent contamination from the farm to the table and to develop new inspection methods based on sound science. He asked for and received an additional \$8 million in the 1994 budget to fund the pathogen reduction program. The Secretary has also called for mandatory safe handling labeling of meat and poultry almost from day one of the new Administration. It is USDA's position that we must keep the consumer informed, and our proposed rule was published November 4. Earlier this spring, the Secretary ordered FSIS to hold six regional public hearings on the two-track approach to inspection, and he convened a national meat inspection summit in November. These initiatives and the many others the Secretary has ordered to reform and modernize meat inspection are included in the charts found at tab A.

This year, USDA adopted a two-track strategic plan that will guide the Agency into the next century. Track I of the plan comprises certain initiatives intended to maximize the performance of the current inspection program and make the most of its resources under existing law. Activities to be pursued in Track I include measures to increase public involvement in decisionmaking, restructuring to maximize effectiveness within available resources, strengthening relations with employee organizations, and raising consumer awareness of food safety and labeling of meat and poultry products.

Also included as an integral part of Track I is the pathogen reduction program -- dubbed the "War on Pathogens." The aim of this program is to reduce the level of pathogens on meat and poultry at key points in the production, distribution, and consumption cycle. Working with APHIS, its sister agency, FSIS is promoting research, animal identification, and model pathogen reduction programs at the pre-slaughter phase of production. Pathogen reduction strategies based on risk analysis will be adopted. Microbiological baseline data is being collected for meat and poultry and intervention techniques will be designed for pathogen reduction.

The Secretary supports the development and implementation of

rapid tests to detect pathogens throughout the food production and processing system. FSIS is introducing new microbial detection and reduction techniques into the meat and poultry inspection program as they become available. Microbiological monitoring will be conducted at critical control points in processing plants and as part of the sanitation inspection program. FSIS will provide the most current food safety information to State enforcement agencies and food handlers. The Agency will also continue to inform consumers of the risks associated with unsafe food handling.

Track II of the strategic plan is a long-term design and development process that will produce the next generation of meat and poultry products inspection regulations. It is a project of immense scope and importance to the health and welfare of the Nation. For this reason, FSIS will initiate Track II development by seeking the best information and ideas that can be brought to bear on the problem. This process has already begun via information gathered through a series of regional public hearings, a meat and poultry conference to determine the future meat and poultry regulatory program, and a plan for an assessment of current and emerging technologies that have the potential to be of use in the production and consumption of safe meat and poultry products.

The Secretary has also recently appointed the Pathogen Reduction Task Force. Membership of the task force includes the Administrators from the Agricultural Marketing Service, the Animal and Plant Health Inspection Service, the Agricultural Research Service, the Cooperative State Research Service, the Extension Service, the Economic Research Service, the Food and Nutrition Service, the Food Safety and Inspection Service, and the Packers and Stockyards Administration. Representatives from the Food and Drug Administration and the Centers for Disease Control have also been invited to participate. The task force is responsible for providing leadership, coordination, and oversight so that the Department's ongoing efforts to reduce pathogens in the meat and poultry supply are realized in a timely, professional, and scientifically supportable manner. Acting Assistant Secretary Patricia Jensen has been appointed by the Secretary to chair the task force.

4. What more needs to be done to further reduce and prevent the risks to public health from meat and poultry products?

The Pathogen Reduction Program undertaken by USDA is a farm-to-table food safety program designed to reduce the presence of pathogens in meat and poultry product. The risk to public health will be reduced by this effort.

In designing and implementing the Pathogen Reduction Program, USDA is faced with several scientific and technological questions that will demand considerable resources and time to resolve.

- Better scientific information and data on the ecology of pathogenic bacteria is needed. This includes increased data collection on the incidence of foodborne illness in the United States. More research is needed on the health effects of Hemolytic Urea Syndrome (HUS). FSIS is working with researchers, scientists, and other professionals on cooperative research efforts to answer these questions.
- Technology and science must be developed to deal with difficulties associated with in-plant microbiological testing for pathogens. When pathogenic bacteria are found in meat and poultry products, the number found is generally very low. Samples are incubated at temperatures where the organisms can multiply. This increases the level of organisms present and, therefore, increases the sensitivity of detection methods. This incubation procedure (also called enrichment), however, also causes a biohazard problem which has the potential to cause increased contamination of food products if not rigidly controlled. A portion of the \$8 million approved to support the Pathogen Reduction Program in Fiscal Year 1994 will be used specifically for method evaluation and development. FSIS encourages commercial development of rapid tests. The Agency recently published in the Federal Register its criteria for rapid test evaluation.

Most food safety experts and scientists advocate the use of Hazard Analysis and Critical Control Point (HACCP) principles to improve food safety. Earlier this year, Secretary Espy announced his intention to mandate HACCP programs for all FSIS inspected meat and poultry establishments. The advances in pathogen detection methods will be important in verifying the critical control points in a HACCP system.

Education is also a key to reducing the risks to public health from food products, including meat and poultry products. USDA published a proposed rule on November 4, 1993 that would require safe handling instruction labels on all raw meat and poultry products. The proposed labels advise consumers of the possible presence of bacteria which can be destroyed through proper

cooking and handling. Proper cooking is currently one of the best defenses against foodborne illness.

USDA's Meat and Poultry Hotline provides consumers with answers to food safety questions. The staff answered over 138,000 calls last year. Throughout the year, the Hotline staff work with the popular media to disseminate information about the prevention of foodborne illness. Radio interviews, magazine articles, and television appearances by Hotline personnel were used to raise public awareness of food safety issues.

Since contamination of meat and poultry can occur if products are mishandled during storage or preparation, the Pathogen Reduction Program also includes activities targeted at the food service and retail level. Recent and current efforts include:

- contributions to FDA's Model Food Code, which many local and state health agencies use to set their health requirements for retail stores;
- a September 2 video conference with FDA staff and USDA's Extension Service for state and local health and regulatory officials concerned with preventing foodborne disease;
- an October mailing of educational materials to restaurant and fast food chain managers with information on pathogens, safe food handling, and food safety training programs;
- production of a video tape for distribution to state and local public health officials on how to test meat in the laboratory for E. coli O157:H7;
- development of a statement of objectives, with USDA's Extension Service, FDA, and the National Restaurant Association, for promoting education of institutional food preparers; and
- distribution of food safety information through the FNS Child and Adult Care Food Program under the Child Nutrition Program.

5. What would an optimal federal food safety system look like? What should be the major components and guiding principles of an optimal system? What options exist for developing and implementing such a system?

After extensive research, FSIS has concluded that the optimal federal food safety system would be comprised of several components. These include: consumer education, partnership with the inspection workforce, implementation of a farm-to-table food safety program, use of the most recent science and technology available, the allocation of resources based on risk, and adequate training and numbers of inspectors. As is evident from review of the Pathogen Reduction Plan and the Track I/Track II strategic plan for inspection modernization, many of the science-based components of the Secretary's plans for improving meat and poultry safety are those recommended by the National Academy of Sciences in its 1985 report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program, and those recommended by the General Accounting Office in its 1992 report, Food Safety and Quality: Uniform, Risk-based Inspection System Needed to Ensure Safe Food Supply.

Secretary Espy is also directing a long-term process that will bring a new inspection program into existence. During the spring and early summer of 1993, six regional hearings were held to gather the opinions and views of as many individuals as possible on the modernization of the inspection system.

On November 9 and 10, USDA sponsored a conference on the "regulatory program of the future." This conference was held as a fact-finding exercise to plan the implementation of the Track II phase of the FSIS strategic plan.

The conference program focused discussion on many parts of the NAS recommendations regarding the "optimal" Federal food safety system. Among these were:

- Allocation of resources for a future regulatory program must be based on risk -- In its 1985 report, NAS recommended that inspection resources be allocated according to the risk posed to public health by slaughter and processing operations. Consequently, the conference considered questions such as: Does the consumer understand the concept of risk? What levels of risk will the public accept? Will the public pay more for reduced risk?
- Public health will have a priority over economic protection -- Under existing statutes, the prevention of economic fraud is on an equal plane with public health protection. For many years a major goal has been to ensure that meat and poultry products are truthfully and accurately labeled. In the future, USDA will take advantage of scientific advances

in fraud detection to lessen the resource intensity devoted to economic fraud and to transfer these resources to public health protection.

- Producers, government regulatory agencies, and consumers will share responsibility to deal with risk in food consumption -- Everyone in the food chain, from farmer through consumer, has a role in keeping the food supply safe. The producer has responsibility for producing animals that are healthy and as free of pathogens as possible using current technology. The government has the responsibility to regulate the meat and poultry industries and ensure that they are producing safe product. The meat and poultry industries have responsibility for handling and preparing food properly. Each segment of distribution must also ensure that meat and poultry remain safe.

A complete report on the outcome of the conference is expected to be released early in 1994.

6. Should the federal government revamp its food safety system, and if so, how?

A complete modernization of the Federal food safety system is necessary. As the Secretary has stated in earlier testimony, the government's food safety efforts must reach from farm to table. They must also be risk- and science-based and incorporate changing public health needs.

As mentioned earlier, the Pathogen Reduction Program (PRP) forms the basis of the Secretary's plans to modernize food safety protection at USDA. Track I of the PRP is designed to maximize the performance of the current inspection system. Under Track I, USDA has begun revamping the food safety system by accelerating initiatives to develop rapid tests for the detection of microbial contamination, by seeking the required legislative authority USDA needs to control pathogens in the food supply through animal identification and traceback, by undertaking baseline studies of pathogens in animals and poultry, by strengthening in-plant inspection procedures, by implementing a comprehensive pathogen reduction program plan, by requiring safe handling instructions on uncooked meat and poultry products, and by launching an aggressive, nationwide food safety education campaign.

Under Track II, which is progressing simultaneously with Track I, FSIS aims to become a science and risk-based system before the year 2000. While the portrait of tomorrow's ideal regulatory program has not yet been characterized, the process of how to identify the best methods to ensure food safety has been determined. It will be an open process that encompasses Total Quality Management Principles and, therefore, centers around broad participation. In the planning stages, FSIS is bringing together its employees and its constituencies -- consumers, industry, the public health and academic communities. The six regional field hearings, and the World Congress for Meat and Poultry Inspection, all held in the past year, are examples of the Track II approach. The program is evolving, and Secretary Espy continues to seek recommendations from all those with an interest in and knowledge of meat and poultry safety.

October 4 letter -- Document Requests

The appendices that follow contain all of the following documents:

1. The status and results of USDA's investigations into the cause, source, and incidence of meat contaminated with E. coli O157:H7, including the results of any on-farm investigations.

We have provided the May 21, 1993, report on the E. coli O157:H7 outbreak in the western states. This report discusses the investigation FSIS conducted on the outbreak, including test results and possible sources. The investigation was extremely helpful in helping us identify further steps that USDA can implement in the future to improve traceback capabilities.

Another document that may provide more information on this topic is the report on the outbreak completed by the Centers for Disease Control (CDC). These reports are found at appendix F.

2. The status and plans for all USDA initiatives to reform the meat and poultry inspection programs, including Tracks I and II; the Pathogen Reduction Program; identification and trace-back of animals; on-farm pathogen reduction and intervention programs; the national microbiological baseline study; the development and validation of rapid tests to detect E. coli O157:H7 and other pathogenic microorganisms; development and implementation of a mandatory Hazard Analysis Critical Control Point inspection approach; implementation of safe handling and cooking labels; the results of USDA's special review of beef slaughter plants; and efforts to estimate the risks of pathogenic microorganisms throughout the food system using dose response models.

USDA will seek changes in FSIS' legislative authority to allow the agency to require mandatory animal traceback and identification. This legislative proposal is in Departmental clearance.

Information on all other initiatives is found in appendix A.

The following documents are also provided:

- 1992 Annual Report of the Secretary to the Congress on meat and poultry inspection. This document includes information on the number of carcasses slaughtered, the

number condemned, compliance activities against violators of FSIS statutes, the types and numbers of rapid tests conducted, the amount of meat and poultry product exported and imported, and other data that may be useful. This report is found at tab G.

- "Evolution to Revolution: New Directions for Meat and Poultry Regulation" -- proposed FSIS strategic plan, May 1993. This document outlines planned activities for the development of the inspection program of the future. This document is found at tab H.
- Pathogen Reduction Program, "The War on Pathogens." This document generally describes each of the initiatives to reduce pathogens, and is found at tab I.
- Budget information detailing FY 1993 and FY 1994 expenditures for FSIS' Pathogen Reduction Program. This information is found at tab J.
- FSIS Administrator's Briefing on the National Academy of Science's Recommendations for meat and poultry inspection. This document describes how FSIS has responded to various recommendations made by the NAS, and is found at tab R.
- Federal Register notice of FSIS evaluation criteria for rapid tests to detect pathogenic bacteria in meat and poultry products. This notice is found at tab O.
- Protocols for National Microbiological Baseline Studies. These are found at tab Q.
- Buchanan, Robert L., and DeRoeve, Catherine M., "Limits in Assessing Microbiological Food Safety," Journal of Food Protection, vol. 56, August, 1993. This article discusses problems associated with developing rapid tests for microbiological pathogens, and is found at tab L.
- Fact sheet on USDA's Special Plant Reviews conducted in the spring and summer of 1993. This includes a list of plants under Progressive Enforcement Action (PEA), plants with multiple citations, and plants with no citations. This information is found at tab K.
- Background and a Question and Answer sheet on Hazard Analysis and Critical Control Point (HACCP) systems. These documents are found at tab S.
- Press release on stricter time and temperature requirements for meat patties cooked in Federally

inspected establishments. It is found at tab T.

- Press releases on public hearings on meat and poultry inspection reform are found at tab U.

3. The level of effort USDA has expended to research, inspect, and regulate pathogenic microorganisms in/on meat and poultry, especially the development of rapid detection tests, since the 1985 National Academy of Science's report, Meat and Poultry Inspection: The Scientific Basis of the Nation's Program.

We have provided the following information:

- a concept paper on the principles of the regulatory program of the future (Track II), found at tab W.
- a program agenda for FSIS' November 9 conference on the regulatory program of the future (Track II), found at tab X.
- Federal Register notice of delegation of research authority to FSIS, found at tab P.
- Federal Register notice of FSIS evaluation criteria for rapid tests to detect pathogenic bacteria, found at tab O.

See also Appendices A-36, A-39, and A-19.

4. The status of USDA's research and regulatory efforts concerning irradiation of meat and poultry.

Irradiation for pork and poultry was approved by FDA in the last decade. Information on irradiation of beef, pork and poultry is found in the appendices at tab N. Specific information on beef irradiation is included in chart A-25 in Appendix A.

5. The status of USDA's efforts to educate and inform consumers about the proper handling and cooking of meat and poultry.

We have included the following information on FSIS' consumer education efforts:

- Consumer education materials related to nutrition labeling and to the proper storage, handling, and cooking of meat and poultry products, including: reprinted articles from Food News for Consumers, backgrounders and press releases on preventing foodborne illness due to E. coli 0157:H7, Listeria monocytogenes, Salmonella enteritidis, and other pathogens.
- Information on media placements and appearances made by USDA's Meat and Poultry Hotline.
- FSIS Backgrounder and Food News for Consumers article on E. coli 0157:H7.
- Press releases and August 16 Federal Register announcement of interim final rule mandating safe food handling labels for raw meat and poultry products.

See also Appendices A-32a through A-35 and Appendix A-22c.

November 8 letter -- Document Requests

1. All news releases, "backgrounders," fact sheets, or other public affair(s) documents issued or released by USDA from December 1992 through the present time concerning E. coli 0157:H7 and/or USDA's initiatives to reform meat and poultry inspection.

These documents are included in the following appendices, along with the following:

- Listing of E. coli 0157:H7 outbreaks that have occurred through November 1, 1993, including place and suspected vehicles of exposure.
- Press releases and comment summary from six public hearings on the FSIS strategic plan and Pathogen Reduction Program.

2. All records written or received by agency employees -- including, but not necessarily limited to, notes, memoranda, correspondence, electronically transmitted communications, and other drafts, analyses or reports -- in any way related to USDA's policy and procedures on "zero tolerance."

The information requested follows in the appendices at tab V.

APPENDIX A

This appendix responds to question 2 in the October 4, 1993 letter from Subcommittee Chairman Towns regarding the status of USDA's efforts to reform and modernize the meat and poultry inspection system.

It includes Appendices A-1 through A-47, expanding on information presented to the Subcommittee previously in a composite chart. Budget figures provided here and in the individual charts reflect agency **estimates** based on actual FY 1993 expenditures. Charts A-1 through A-7 provide estimates that include staff years. The budget estimates in charts A-8 through A-47 **do not** include staff years, but instead reflect expenditures for supplies and equipment, travel, printing, and other administrative costs. These estimates also reflect base level funding as well as special appropriations made for pathogen reduction activities.

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
<u>LIVE ANIMAL ACTIVITIES</u>			
Assessment of Exposure to <u>E. coli</u> O157:H7	\$165,000	2.2	A-1
Pennsylvania Salmonella <u>enteritidis</u> (SE) pilot project	600,000 (FY93) 900,000 (FY94)	12.0	A-2a
National Dairy Heifer Evaluation Project (NDHEP)	269,104 (FY94)	3.1	A-2b
NDHEP Follow-up	4,000 (FY94)	.25	A-2c
Develop National Food Safety Agenda document	45,000 (FY94)	.75	A-3a
Salmonella enteritidis case surveys in dairy cattle	N/A	existing	A-3b

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff</u>	<u>Yrs</u>	<u>Appendix</u>
<u>Salmonella enteritidis</u> (SE) Traceback Program	3,400,000 (FY93) 4,100,000 (FY94)	existing		A-4a
Targeted on-farm investigations of <u>E. coli</u>	6,500	.10		A-4b
<u>Salmonella enteritidis</u> (SE) research	440,000	N/A		A-5
Draft legislation enabling on-farm investigations	N/A	existing		A-6
Pathogen prevention research (vaccines and probiotics)	200,000	N/A		A-7a
Analyze data from state universities, vet. labs, and FSIS database	N/A	1.25		A-7b
Calif. Cull Dairy/Beef quality assurance model program	250,000	3.0		A-7c
Bovine Tuberculosis in Cervidae Herds	N/A	existing		A-7d
Scrapie Flock Certification Program	N/A	existing		A-7e
Pennsylvania Egg Quality Assurance Program	N/A	existing		A-7f
<u>SLAUGHTER PLANT ACTIVITIES</u>				
Publish proposed rule for mandatory record-keeping	10,000	.25		A-8

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff</u>	<u>Yrs</u>	<u>Appendix</u>
Steer/Heifer Microbiologic Baseline Study	625,000 (FY93 base)	15.5		A-9a
Cow/Bull Microbiologic Baseline Study	625,000 (FY93 base)	15.5		A-9b
Broiler Chicken Microbiologic Baseline Study	625,000 (FY93 base)	7.5		A-9c
Turkey Microbiologic Baseline Study	625,000 (FY93 base)	7.5		A-9d
Market Hog Microbiologic Baseline Study	625,000 (FY93 base)	15.5		A-9e
Targeted Microbiologic Investigations	800,000 (FY93 base)	TBD		A-9f
Use data to establish pathogen reduction targets	see A-9a to A-9f	see A-9a to A-9f		A-9g
Disabled Cow Microbiologic Sampling	10,000	3.5		A-10
Microbiological Equipment Sampling in Pre-op. Sanitation	3,487,000 (FY94)	see chart		A-11
Beef Slaughter Process Control	100,000	existing		A-12
Contract Research Studies	1,000,000	N/A		A-13a
Beef Trimming vs. Washing	108,000	N/A		A-13b
Develop clean meat program for all meat species	10,000 (FY94)	.25		A-14a

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Develop clean poultry program for all poultry classes	10,000 (FY94)	.25	A-14b
Revise carcass Acceptable Quality Level directive to eliminate fecal and ingesta defects	10,000 (FY94)	.25	A-14c
Immediate action to implement cattle clean meat program in beef slaughter plants	390,000	10.0	A-14d
Instructions to field inspectors on mandatory trimming in slaughter operations	existing	.01	A-14e
Implement stronger pre-operational sanitation program in meat slaughter plants	992,000	20.0	A-14f
Revise Sanitation Handbook for inspectors and supervisors	250,000	5.0	A-14g
Publish a directive allowing for application of organic acid sprays	4,000	.10	A-15a
Publish a directive allowing the use of trisodium phosphate (TSP) as antimicrobial agent	14,000	.35	A-15b
Pilot test and evaluate effectiveness and feasibility of dehairing cattle prior to hide removal and evisceration	10,000	.25	A-16
Examine current criteria for classifying veterinary assignments in bovine slaughter plants	27,000	.10	A-17

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Hold HACCP Roundtable	25,000	.50	A-18
Develop rapid microbiologic methods for laboratory or in-plant use	1,000,000	existing	A-19
<u>PROCESSING PLANT ACTIVITIES</u>			
Ground Beef Survey	145,000	4.5	A-20
Critical Control Point (CCP) microbiologic testing of ground beef patties	100,000	.50	A-21
Conduct focus group research for safe handling instruction labels	50,000	.10	A-22a
Achieve consensus with FDA on storage, handling and cooking parameters	N/A	.10	A-22b
Rulemaking for safe handling instruction labels	21,250	1.5	A-22c
Issue regulations specifying heat processing, cooling, handling, labeling, and storage requirements for meat products	10,000	.25	A-23a
Issue directives to inspection personnel identifying tasks, methods, and procedures for inspecting cooked patties	60,000	.25	A-23b

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Mandate recordkeeping for finished products	10,000	.25	A-24
Consider submission of a Food Additive Petition to FDA permitting irradiation of raw beef products	150,000	N/A	A-25
Establish time and temperature requirements to reduce bacteria proliferation in ground meat and meat trimmings	80,000	2.0	A-26
Revise Boreless Meat Reinspection Directive to make fecal and ingesta contamination an automatic failure	10,000	existing	A-27a
Revise Sanitation Handbook for inspectors and supervisors	250,000	existing	A-27b
Devise uniform pre-operational sanitation inspection program for all processing plants	existing	existing	A-27c
<u>FOOD SERVICE AND RETAIL ACTIVITIES</u>			
Cooperate with FDA to produce teleconferences on food safety topics for state and local health officials	50,000	existing	A-28
Provide technical and resource assistance to states for enforcement efforts.	existing	.25	A-29a

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Produce video tape for state and local health officials demonstrating proper method for analyzing meat and poultry samples	15,000	existing	A-29b
Educate fast food chain and restaurant employees	150,000	existing	A-30
Coordinate with HHS Office on Aging to develop and distribute food safety education materials to food preparers serving senior citizens	50,000	.25	A-31a
Produce and distribute food safety education materials to day care centers and schools	225,000	.25	A-31b
<u>CONSUMER AWARENESS ACTIVITIES</u>			
Improve understanding of the risks involved in unsafe food handling practices and practical food safety advice steps for consumers	50,000	.25	A-32a
Conduct a public awareness campaign in conjunction with implementation of the Safe Food Handling Label final rule	150,000	.75	A-32b
Produce a video tape on safe food handling targeted to pregnant women and mothers with small children (Women, Infants and Children Program participants and others)	75,000	.75	A-33a

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Develop a food safety education program 300,000 targeted to children aged 4-10	300,000	.75	A-33b
Work with various constituent groups to promote existing and new consumer education materials	100,000	.50	A-34
Publish "Margin of Safety" project report, "A Quick Consumer Guide to Safe Food Handling" and "Preventing Foodborne Illness," for Extension agents, local public health and other food safety educators	120,000	3.0	A-35
<u>FEDERAL GOVERNMENT PROCESS</u>			
Design a new, risk-based, farm-to-table regulatory program for meat and poultry production	2,500,000	8.0	A-36
Hire physician to head public health division of FSIS	150,000	1.0	A-37
Detail FSIS liaison officer to CDC to help integrate meat and poultry safety issues into CDC planning and operations	66,609	1.0	A-38
Publish regulation permitting agencies other than ARS to contract for research	existing	N/A	A-39
Form interagency task force on pathogen reduction	existing	.50	A-40

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff Yrs</u>	<u>Appendix</u>
Employ additional in-plant inspectors	4,000,000 (FY93) 10,000,000 (FY94)	200 per year	A-41
<u>PROGRAM REVIEW AND INTERNAL ASSESSMENT ACTIVITIES</u>			
Establish Review & Assessment program in FSIS	2,560,000	45.0	A-42
Conduct investigations of alleged program breakdowns	356,000	6.2	A-43a
Track complaints and referrals	82,000	2.0	A-43b
Conduct special project reviews	671,000	0.0	A-43c
Review 1,000 federally inspected meat and poultry plants, including 650 with history of non-compliance	2,100,000	24.0	A-44
Develop profile of non-compliant plants	203,000	3.5	A-45
Conduct reviews of plants involved in supply and production of beef for hamburger	165,000	2.0	A-46
<u>NEW INITIATIVES</u>			
Develop principles and models for quantitative risk assessment of microbiological hazards	150,000	6.0 - 8.0	A-47

<u>ACTIVITY</u>	<u>Funding</u>	<u>Staff</u> <u>Yrs</u>	<u>Appendix</u>
Conduct reviews of all plants operating under the New Turkey Inspection System	18,000	2.0	A-48

APPENDIX A-1
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Determine the sources and incidence of E. coli 0157:H7 and other pathogens

Activity: Assessment of exposure to E. coli 0157:H7. Emphasis is being placed on assessing the role of the preharvest component of the farm-to-consumer food safety continuum in influencing human exposure, particularly the exploration of potential risk factors for cattle. In addition, components of the ground beef industry, including meat composition, regional differences, imports, consumption patterns, and trends are being evaluated to help explain why human 0157 incidence has increased and to address issues involving future exposure.

Start Date: 3/93 **End Date:** Ongoing **Method of Reporting Final Results:** Final Report to be issued by 3rd quarter FY 94.

Staff Years Expended or Required for Completion: 2.2

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$165,000

Evaluation Mechanisms in Place or Planned: Macroepidemiologic study of data pertaining to the importance of 0157 as a foodborne pathogen.

Status: Data collection and analysis have been completed, and assessment and interpretation are underway.

Findings: Final report to be issued during 1994.

Future Action: The 0157 document will be distributed to interested parties for review and comment. Internal APHIS/FSIS review is ongoing. Presentations will be given to other interested parties. APHIS/Centers for Epidemiology and Animal Health will maintain communications as needed with other Federal agencies, States and other interested parties.

APPENDIX A-2a
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Conduct epidemiological field studies for risk analysis, control and intervention.

Activity: Pennsylvania Salmonella enteritidis (SE) Pilot Project

This pilot project is a cooperative effort of the Pennsylvania egg industry, Pennsylvania Department of Agriculture and the USDA to:

1. reduce the number of SE cases and outbreaks due to shell eggs; and
 2. find out as much as possible about how to prevent and control SE in egg layer flocks.
- The pilot is projected to operate for 2 years. Information generated will be used to develop a broader Egg Quality Assurance Program in Pennsylvania and other areas where SE in egg layer flocks is a problem.

Start Date: 4/92 **End Date:** 4/94 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: Project required 12 staff positions - April 1992-March 1994

Estimated Expenditures (including dates) or Appropriation Required for Completion: Annual budget FY'93 - \$600,000; FY'94 - \$900,000

Evaluation Mechanisms in Place or Planned: Progress is measured by essential information generated and number of SE outbreaks traced back to Project Flocks (to date - none).

APPENDIX A-2a (Cont.)

Status: Project considered to be ahead of schedule - will probably phase out and be replaced by the Pennsylvania Egg Quality Assurance Program in early 1994. Evaluation will be based on completion of objectives formulated at beginning of Project.

Findings: Through this project, preliminary critical control points have been identified that will ultimately be used to develop pathogen prevention strategies for SE. The strategies will be the foundation of a flock certification program.

Future Action: In April 1994 project will be merged into the Pennsylvania Egg Quality Assurance Program.

APPENDIX A-2b
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Conduct Epidemiological Field Studies for Risk Analysis, Control and Intervention.

Activity: National Dairy Heifer Evaluation Project (NDHEP)

Between 1991 and 1992, the Centers for Epidemiology and Animal health, in conjunction with the National Veterinary Services Laboratories, the Operational Support Staff, and the four regional offices of Veterinary Services, conducted a survey to evaluate the management practices and general health of dairy heifers, and any associations that might exist between the two. Most of the study focused on pre-weaned dairy heifers under two months of age. Specifically, 6,894 calves were tested for *E. coli* and in 25 calves the pathogen was found. Data collection for a follow-up study conducted to characterize *E. coli* 0157:H7 was completed in early 1993. The NDHEP is the basis for the national prevalence estimates for *E. coli* 0157:H7, *Salmonella* *se.*, and *Cryptosporidia*.

Start Date: 3/91 **End Date:** 7/92 **Method of Reporting Final Results:** A preharvest food safety commodity report utilizing data from these studies and other sources to identify trends is expected by June 30, 1994.

Staff Years Expended or Required for Completion: 3.1

Estimated Expenditures (including dates) or Appropriation Required for Completion: FY 94 = \$269,104 (this amount does not include contingency funds)

Evaluation Mechanisms in Place or Planned: A comparison of the data collected by the National Agricultural Statistics Service and loss estimates in existing literature and databases.

Status: The first reporting of information to the public was 12/91. Analysis, interpretation, and reporting of results are ongoing. The NDHEP follow-up study was implemented in FY 93 to try to characterize specific risk factors on dairy farms for 0157. Data collection was initiated in 3/93 and analysis, interpretation,

APPENDIX A-2b (Cont.)

and reporting of results are ongoing. Data collection for the follow-up study will be completed in 7/94. The first reporting of information from the follow-up study will be available to the public 11/93.

Findings: The national survey of pre-weaning dairy heifers demonstrated that:

- * there is a very low prevalence of E. coli 0157:H7, less than 1 percent in calves and about 5 percent in herds, as identified by fecal culture.
- * the prevalence of E. coli 0157:H7 appears to be higher in older calves up to 4 months old.
- * there appears to be no regional variation in the incidence of E. coli 0157:H7 as positive calves were found all around the United States, albeit in very small numbers.
- * fecal isolation of E. coli 0157:H7 was not associated with clinical signs of diarrhea in dairy calves.
- * E. coli 0157:H7 shedding was significantly associated with weaning.
- * identification of E. coli 0157:H7 from a carcass and subsequent tracing of the carcass to the herd of origin is not predictive of the herd status on follow-up sampling.
- * each of the six currently recognized species of Cryptosporidium infects a variety of hosts - birds, reptiles, and mammals, including bovines and humans. Cryptosporidium occurs in most large- and medium-sized herds, but a small percentage of herds with less than 100 cows may be free of the agent.
- * there appears to be no regional variation in the incidence of Cryptosporidium as positive calves were found all around the United States. It may be present on more than 80 percent of farms in every region.
- * the individual animal prevalence rate of Salmonella sp. is about 2.1 percent.
- * the Salmonella sp. serotype found most often was S. Typhimurium (27.6 percent of the positive samples), followed by S. dublin (10.3 percent of the positive samples).

Future Action: None

Comments:

APPENDIX A-2c
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Conduct Epidemiological Field Studies for Risk Analysis, Control and Intervention Strategies

Activity: Evaluation of dairy herd for E. coli based on traceback from FSIS slaughter sample. After initially isolating E. coli in the herd, retesting resulted in no animals positive for E. coli 0157:H7.

Start Date: 10/92 **End Date:** Completed

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures (including dates) or Appropriation Required for Completion: No further ongoing cost. Initial \$4,000 lab costs.

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Terminated

Findings: Because E. coli 0157:H7 was not isolated in the herd, further study would not yield significant information useful to pathogen reduction efforts.

Future Action: None

Comments:

APPENDIX A-3a
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activities

Initiative: Conduct Comprehensive Research

Activity: Work with Agricultural Research Service, the Cooperative State Research Service, and universities to identify and prioritize research needs and collect baseline data on the presence of pathogens and monitor for trends, geographic differences and causal links. Develop a National Food Safety Agenda (NFSA) document and FY 94-95 Preharvest Food Safety Operational (PFSO) plans that will be used to help producers deal with pathogen problems on the farm.

Start Date: 3/93 **End Date:** 3/94 **Method of Reporting Final Results:** The NFSA document will be published and distributed to interested groups for comment and feedback. The document will also be discussed at a national meeting to assess the accuracy and appropriateness of the contents with interested groups. Meetings with allied Federal agencies and interested parties regarding APHIS' direction and progress with preharvest food safety will be ongoing. APHIS intends to interact with appropriate groups on an annual basis to ensure program accuracy and completeness.

Staff Years Expended or Required for Completion: NFSA document = .75

Estimated Expenditures or Appropriation Required for Completion: NFSA document: \$45,000

Evaluation Mechanisms in Place or Planned: The APHIS Legislative and Public Affairs staff is keeping Veterinary Services apprised on movement of the National Food Safety Agenda document through the clearance process. The document is slated for completion during the 2nd quarter of FY 94. The document will be distributed for public review. Meetings will be held with interested parties to discuss the contents of the draft document. The APHIS FY 94 and FY 95 operational plans consist of specific preharvest food safety related goals. Each goal is a measurable entity, with the overall effectiveness of the Agency in accomplishing food safety objectives being assessed by evaluating the number of operational plan goals completed.

APPENDIX A-3a (Cont.)

Status: "The APHIS Perspective on a National Food Safety Agenda" document, which provides an overview of the preharvest food safety services APHIS can provide, is in the final stages of receiving Departmental clearance for publication. It is anticipated that the final document will be printed and ready for distribution during the 2nd quarter of FY 94.

The APHIS Food Safety Management Committee has completed an FY 94 and FY 95 preharvest food safety operational plan for Veterinary Services implementation. The Deputy Administrator for Veterinary Services will be conducting a final review of the operational plan by the end of the 1st quarter, FY 94. Approximately 40% of the operational plan objectives for FY 94 are currently underway.

Findings: Not applicable

Future Action:

Comments:

APPENDIX A-3b
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Research

Initiative: Conduct Comprehensive Research

Activity: Salmonella enteritidis (SE) Surveys of Poultry and Eggs. These national surveys formed the basis for understanding the extent of SE infection in egg-laying flocks. The current SE traceback program was originally established based on a belief that a small number of flocks were infected. These studies show the assumption to be incorrect and demonstrated the need to redesign and expand the program to meet the problem.

Start Date: 1990 **End Date:** 1991 **Method of Reporting Final Results:** Reports published:

Occurrence of Salmonella enteritidis in the U.S. Commercial Egg Industry: Report on a National Spent Hen Survey: E. D. Ebel, M. J. David, and J. Mason: AVIAN DISEASES 36:646-654, 1992

Occurrence of Salmonella enteritidis in Unpasteurized Liquid Egg in the United States: E.D. Ebel, J. Mason, L. A. Thomas, K. E. Ferris, M. G. Beckman, D. R. Cummins, L. Schroeder-Tucker, W. D. Sutherland, R. L. Glasshoff, and N. M. Smith-Hisler: AVIAN DISEASES 37:135-142, 1993

Staff Years Expended or Required for Completion: Included in the activities of SE Task Force 1990-91.

Estimated Expenditures (including dates) or Appropriation Required for Completion: Included in FY 94 funding of \$4.1 million.

Evaluation Mechanisms in Place or Planned:

Status: Completed in 1991

APPENDIX A-3b (Cont.)

Findings: Report on a National Spent Hen Survey: The distribution of *S. enteritidis* phage types was consistent with data reported by others. Regionally, the estimated prevalence of *S. enteritidis*-positive houses (i.e., at least one positive sample found in a house) for the Northern, Southeastern and Central/Western regions was 45%, 3%, and 17%, respectively. Overall, the prevalence of *Salmonella*-positive houses was 86%.

Unpasteurized Liquid Egg Study in the U.S.: On a regional basis, the Northern Region of the United States had the highest *S. enteritidis* recover, with 20% of the sample submitted from plants in that region culture-positive for this serotype. *Salmonella enteritidis* positives from the Southeast, Central, and Western regions were 10%, 15%, and 6% of the samples submitted, respectively.

Future Action:

Comments:

APPENDIX A-4a
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Conduct on-farm investigations

Activity: The *Salmonella enteritidis* (SE) traceback program tests poultry flocks implicated in human outbreaks of SE and requires that eggs from positive flocks be diverted to processing. Flocks are monitored until determined to be negative for SE.

Start Date: 2/90 **End Date:** ongoing **Method of Reporting Final Results:** Bi-weekly reports, summary reports, press releases, and fact sheets.

Staff Years Expended or Required for Completion: As required by outbreaks and traceback activities.

Estimated Expenditures (including dates) or Appropriation Required for Completion:
FY 93 = \$3.4 million; FY 94 = \$4.1 million

Evaluation Mechanisms in Place or Planned: Monitoring of infected flocks and monitoring of trends in human outbreaks.

Status: Ongoing

APPENDIX A-4a (Cont.)

Findings: Since the start of the SE traceback program in February, 1990, 242 human SE outbreaks have been monitored by the Animal and Plant Health Inspection Service SE Task Force. Eggs were implicated in 75 of these outbreaks. Traceback operations were initiated to the flocks of origin for all of these outbreaks. In 25 outbreaks, the source flock could not be identified. In 2 outbreaks, egg traces are still in operation. Traces from the remaining 48 outbreaks led to 35 flocks. Nine had been depopulated before it was possible to test them. Three were negative on tests for SE and 23 were positive for SE. As a result, more than 2.2 billion eggs have been diverted from these flocks to pasteurization plants.

Future Action:

Comments:

APPENDIX A-4b
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Conduct On-Farm Investigations

Activity: Assist public health officials in conducting a targeted on-farm investigation of two raw milk herds in Oregon that were identified as the possible source of *E. coli* outbreaks. Data may help to confirm current assumptions about sources and good preventive measures that can be quickly implemented. Specifically, two hypotheses will be tested by this risk factor study:

- (1) are herds which graze on lands irrigated with slurry or fed ionophores more likely to be colonized by *E. coli* O157:H7?
- (2) does the prevalence of *E. coli* O157:H7 increase during transport and can the new detected genetic fingerprint patterns account for some of the increase?

Start Date: 2/93 **End Date:** 8/94 **Method of Reporting Final Results:** Laboratory reports and summary evaluation.

Staff Years Expended for Completion: .1

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$6,500

Evaluation Mechanisms in Place or Planned: Analysis of collected data and evaluation of hypotheses.

Status: The raw milk herds that are being used will be tested by fecal swab culture of each animal in the herd every 4 to 6 weeks, and 60 post-weaned heifers will be sampled monthly for 6 months from March to August.

Findings: Data still being collected.

Future Action: Testing and evaluation of the *E. coli* O157:H7 status in the implicated raw milk herds will continue for a minimum of 1 year, until August 1994.

APPENDIX A-5
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Develop Rapid Methods for SE diagnosis

Activity: For Salmonella enteritidis (SE) the following research was funded:

1. Dr. Keller - University of Pennsylvania
 - to develop Enzyme Link Immunosorbent Assay (ELISA) test using monoclonal antibodies for rapid serological diagnosis of SE in eggs. (\$50,000)
2. Dr. Goldsby - University of Massachusetts
 - to develop lift assays on cultures of eggs to permit rapid diagnosis of SE from initial cultures. (\$50,000)
3. Dr. Saeed - Purdue University
 - to develop methods for the rapid diagnosis of SE in eggs by culture techniques; to develop serological methods to diagnosis SE in egg layer flocks (egg yolk antibody test). (\$200,000)
4. Dr. Benson - University of Pennsylvania
 - to provide laboratory services for the Pennsylvania SE Pilot Project and to investigate the use of phage typing and plasmid analysis in identifying strains of SE in flocks causing SE outbreaks. (\$100,000)
 - to follow a naturally infected flock of egg layers to determine infection and transovarial transmission patterns. (\$40,000)

APPENDIX A-5 (Cont.)

Start Date: see below **End Date:** see below **Method of Reporting Final Results:** see below

Staff Years Expended or Required for Completion: Not applicable

Estimated Expenditures (including Dates) of Appropriation Required for Completion: \$440,000

Evaluation Mechanisms in Place or Planned: Compliance with objectives listed in the projects, site visits, and review of publications.

Status: Dr. Keller - Completed, 1993; Dr. Goldsby - Completed, 1993; Dr. Saaed - ongoing to Feb, 1994; Dr Benson - Ongoing to Feb, 1994.

Findings: Developed a functional monoclonal ELISA test for SE. Developed an operational lift assay for SE.

Future Action: Dr. Goldsby's and Dr. Benson's research projects will continue in the next calendar year.

Comments:

APPENDIX A-6
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Establish methods for the identification and traceback of animals.

Activity: Draft legislation to facilitate on-farm prevention programs and permit better investigation of the source of E.coli 0157:H7 and other pathogens.

APHIS and FSIS have prepared draft legislation to, among other things, provide the legislative authority needed to facilitate on-farm prevention programs and permit better investigation of the source of E.coli 0157:H7 and other health problems. This legislative package includes animal identification and traceback capability.

The draft bill also includes amendments to several animal health laws that change the definition of "disease" to give the Secretary a more complete range of authorities to address food safety on the farm and complete the farm to table continuum envisioned under the Department's Pathogen Reduction Plan. The new definition of disease will encompass not only those diseases that cause health problems, but any disease or health condition that affects production or marketing of livestock and poultry. This will allow APHIS to provide producers with a full range of health services, advice, and assistance.

APHIS has some traceback capability and authority under existing statutes. Traceback of Salmonella enteritidis to flocks of origin is one example. The legislative package will provide a more comprehensive authority.

Start Date: summer 1993 **End Date:** ongoing **Method of Reporting Final Results:** Established legislative process.

Staff Years Expended or Required for Completion: See below.

APPENDIX A-6 (Cont.)

Estimated Expenditures (including dates) or Appropriation Required for Completion: (Existing staff years and resources will be used as needed.)

Evaluation Mechanisms in Place or Planned:

Status: Drafting completed and placed in clearance.

Findings: Not applicable

Future Action: Established legislative process.

Comments: This is a companion activity to item A-8 under Slaughter Plant Activities and item A-24 under Processing Plant Activities.

APPENDIX A-7a
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Develop On-farm Pathogen Prevention Program/models.

Activity: Support various research initiatives for pathogen reduction, including prevention of *E. coli* 0157:H7 in live animals, *Salmonella enteritidis* (SE) reduction activities, new vaccine development, and probiotics (probiotics is a preparation of non-harmful intestinal bacteria used to exclude undesirable intestinal bacteria.)

The Animal and Plant Health Inspection Service has funded a project at Purdue University to develop methods for the rapid diagnosis of SE in eggs by culture techniques and to develop serological methods to diagnosis SE in egg layer flocks (egg yolk antibody test).

Start Date: 2/93 **End Date:** 3/94 **Method of Reporting Final Results:** published reports

Staff Years Expended or Required for Completion: Project is contracted to Purdue.

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$200,000

Evaluation Mechanisms in Place or Planned: See Initiative on Develop Rapid Methods for SE Diagnosis at A-5.

Status: Ongoing

Findings:

Future Action:

Comments:

APPENDIX A-7b
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Develop On-farm Pathogen Prevention Program/models.

Activity: Integrate and analyze data from State universities, veterinary diagnostic laboratories and FSIS database on pathogens. Activities will include an ARS-FSIS-APHIS food safety risk analysis and research priorities meeting, a food safety research priorities meeting, a food safety research update meeting, and a research sabbatical for identifying APHIS preharvest food safety research priorities.

APHIS is participating with ARS and FSIS in planning sessions to identify FY 94 risk assessment priorities for foodborne pathogens, as well as research priorities for preharvest food safety programs. In addition, APHIS participated with these agencies in the annual Food Safety Research Program Planning Workshop. The quantitative risk assessment priorities meeting was conducted on November 18, 1993, the research priorities setting session was held on November 29 & 30, 1993, and the research program planning workshop was held on December 1 & 2, 1993. APHIS also plans to sponsor a university sabbatical, with the incumbent responsible for establishing a mechanism to monitor preharvest food safety research activities, and to identify emerging research needs.

Start Date: See above **End Date:** See above **Method of Reporting Final Results:** Published research reports.

Staff Years Expended or Required for Completion: Interagency research priority setting and monitoring: 1 staff year. Sabbatical: 00.125 staff year to set-up. 1 staff year for sabbatical.

Estimated Expenditures (including dates) or Appropriation Required for Completion: Setting and maintaining research priorities: \$80,000 (estimated.) Establishing research priority monitoring mechanism: \$90,000 (estimated.)

APPENDIX A-7b (Cont.)

Evaluation Mechanisms in Place or Planned: Risk Assessment and research priority setting will be evaluated at the end of the fiscal year based on : (1) whether needed research was initiated, maintained, or completed for the purpose of reaching targeted food safety objectives; and (2) by annually reassessing whether targeted research and risk assessment priorities mirror human foodborne illness outbreak data, consumer concerns, and commodity group needs. The utility of the research monitoring mechanism established through the sabbatical will be evaluated by comparing declining foodborne illness outbreaks for targeted pathogens (over time), as targeted research issues are addressed.

Status: The risk assessment, research priorities and research planning workshops have already been held. Allied agencies will meet as the need arises during the fiscal year to review progress on accomplishing risk assessment and research priorities. Hosting a university sabbatical will consist of identifying a faculty member with the expertise and ability to participate in the program, reaching an agreement with the host institution regarding the terms of the sabbatical, and setting a start date for the agreement to commence.

Findings: Not applicable.

Future Action: Agency scientists will develop a research priority list and determine needs on a continuing basis.

Comments:

APPENDIX A-7c
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Develop On-farm Pathogen Prevention Program/Models

Activity: Work with producers to introduce voluntary, industry supported herd certification programs.

APHIS, along with FSIS, FDA, Extension Service, State agency counterparts, dairy industry representatives, university researchers, and private practice veterinarians, have established a model program for constructing multidisciplinary teams to address preharvest food safety issues. One example is the California Cull Dairy\Beef quality assurance model program. The California team's present activities focus on reducing the incidence of drug residues in cull dairy cows. The team also works with the dairy industry to identify food safety research needs, and coordinates with university team representatives to ensure that targeted priorities are addressed. The multidisciplinary team has been functioning for a year and a half. Because food safety assurance is an ongoing process, the model multidisciplinary team and associated programs, will be expanding over time to address additional food safety issues and can be used as a model for pathogen reduction activities. A completion date will not be set.

Start Date: 12/92 **End Date:** Not applicable **Method of Reporting Final Results:** Not applicable

Staff Years Expended of Required for Completion: Three staff years per year.

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$250,000 for surveillance (funding is shared among the various government and industry representatives).

APPENDIX A-7c (Cont.)

Evaluation Mechanisms in Place or Planned: Monitoring for adulteration of the food supply. Progress on the multidisciplinary team program is defined by: charting a decrease in the incidence of drug residues in cull dairy cows, charting an increase in the number of residue positive cows that can successfully be traced to the farm of origin, and noting a steady increase in the number (raw and percentage based) of the dairy operations in southern California participating in the program. The team will expand its activities over time to include traceback and control program development for biological pathogens. Methods for assessing biological pathogen program success will be defined at the time of traceback and control program design.

Findings: Substantial reductions in residues are being achieved.

Future Action:

Comments:

APPENDIX A-7d
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Developing On-farm Pathogen Prevention Program/Models

Activity: Bovine Tuberculosis in Cervidae Herds

APHIS, working with State agency counterparts, cervid industry representatives, private practice veterinarians, university researchers, and other government agencies, developed comprehensive voluntary guidelines for the control of tuberculosis in Cervidae, which includes primarily deer and elk. These guidelines were intended to serve as the basis for a voluntary control program for tuberculosis in farmed Cervidae, pending the development of a Uniform Methods and Rules (UMR) for the Eradication of Tuberculosis in Cervidae (UMR). This UMR was completed and accepted by the U.S. Animal Health Association in October 1993. Under this UMR, individual cervids and cervid herds, through various prescribed testing protocols, will become qualified for interstate movement. Tests to be used, infected animal and herd management, and interstate movement requirements are described. Regulations are being drafted to include Cervidae in Title 9 CFR.

Start Date: 10/93 **End Date:** ongoing **Method of Reporting Final Results:** Monitoring incidence of TB in Cervidae

Staff Years Expended or Required for Completion: No identified or specified staff years.

Estimated Expenditures (including dates) or Appropriation Required for Completion: Not specified at this time.

APPENDIX A-7d (Cont.)

Evaluation Mechanisms in Place or Planned: Initial progress can be measured by the number of States adopting the UMR, their formal initiation of a Cervidae program and the process each makes in carrying out the procedures required for an effective eradication effort. Later progress will be measured by herds tested and freed of the disease, reduction in tuberculosis prevalence by state and nationally and, eventually by declaration of cervids as free of the disease. The elimination of tuberculosis from farmed Cervidae will be verified through on-farm testing and slaughter surveillance.

Status: Guideline completed; regulatory program being implemented.

Findings: Testing and traceback indicate the presence of TB in Cervidae herds that may infect or reinfect cattle herds that are free of TB.

Future Action:

Comments:

APPENDIX A-7e
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Develop On-farm Pathogen Prevention Program/Models

Activity: Voluntary Scrapie Flock Certification Program (VSFCP)

Sheep producers, sheep breed associations, the American Sheep Industry Association, the American Farm Bureau, and other allied animal health groups along with APHIS established the VSFCP through the process of negotiated rulemaking. The goal of the program is to certify that flocks have not been exposed to scrapie nor have they had clinical signs of scrapie for a minimum of five years. The earliest that a flock participating in the program could be certified would be October 1, 1997. This animal health certification program can serve as a model for certification programs related to human pathogens.

Start Date: 10/93 **End Date:** See above **Method of Reporting Final Results:** Final rule adopted -- certification program is being implemented.

Staff Years Expended or Required for Completion: Flock participation will determine extent of staff years required.

Evaluation Mechanisms in Place or Planned: Progress in the VSFCP will be measured by the interest and participation of producers. The number of enrolled flocks at the various program levels will be indicative of the success of the program as participation in the certification process is voluntary.

APPENDIX A-7e (Cont.)

Evaluation upon completion: The VSFCP will be an ongoing activity with no endpoint. As more flocks become certified, more flocks will likely enroll in the program. Controlling the spread of scrapie will be enhanced as the number of certified flocks increases.

Status: Final Rule was adopted.

Findings:

Comments: This effort serves as a model for a pathogen prevention program.

APPENDIX A-7f
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES

Pathogen Reduction Activities

TYPE OF ACTIVITY: Live Animal Activity

Initiative: Developing On-farm Pathogen Prevention Program/Models

Activity: The Pennsylvania Egg Quality Assurance Program (PEQAP) is a voluntary industry program intended to minimize Salmonella enteritidis (SE) contamination of eggs through producer implementation of management practices most likely to prevent SE contamination. This program should cover up to 200 flocks (15 million egg layers) within a 6-month period, and the total egg layer population of Pennsylvania by the end of 1994. This model preharvest program can be extended to other SE problem areas as needed.

Start Date: 10/93 **End Date:** ongoing **Method of Reporting Final Results:** annual reports to be published

Staff Years Expended or Required for Completion: Estimated rate of 10-12 staff years per year.

Estimated Expenditures (including dates) or Appropriation Required for Completion: Approximately \$700,000 in FY 94.

Evaluation Mechanisms in Place or Planned: Basis of human outbreaks; results of testing; traceback to flocks; number of positive flocks; acceptance of industry.

Status: The Pennsylvania Egg Quality Assurance Program was initiated in October 1993 and went into full operation January 1994.

Findings:

Future Action:

Comments: This program will succeed the cooperative effort between Pennsylvania and the USDA on SE risk analysis, control and intervention. Companion to item A-2.

APPENDIX A-8
 FOOD SAFETY AND INSPECTION SERVICE
 SCIENCE AND TECHNOLOGY DIVISION
 INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Mandate recordkeeping in inspected plants to support traceback capability

Activity: This initiative seeks to provide traceback capability by issuing regulations which will require that inspected plants maintain sufficient records to allow lots of finished products to be traced to specific animals slaughtered.

Start Date: 3/93 **End Date:** Spring '94 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures or Appropriations Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: In-plant inspector will monitor plant's records for completeness and accuracy.

Status: Proposed regulation is in final Department clearance.

Findings: Not applicable

Future Action: Comment analysis and publication of a final rule; implementation of a final rule; and compliance monitoring.

Comments: This is a companion activity to item A-24 under Processing Plant Activities and item A-6 under Live Animal Activities.

APPENDIX A-9a
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Studies

Activity: Steer/Heifer Survey -- This survey will provide a microbiological "picture" or profile of steer and heifer carcasses from Federally inspected plants. It will indicate whether certain pathogens are present and if so, at what level. This data will be used to document changes in the profile over time as inspection policies and procedures change, and will lead to further, more specialized studies that will evaluate specific products or the effect of specific decontamination intervention strategies.

Start Date: 10/92 **End Date:** 12/93 **Method of Reporting Final Results:** Final Report in January 1994.

Staff Years Expended or Required for Completion: 15.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$625,000 (base FY93 funds)

Evaluation Mechanisms in Place or Planned: Trial phase of 90 days completed 11/93 to ensure proper sample collection and analytical procedures are understood. Laboratory forms are routinely checked for accuracy. A system is in place for determining acceptability of samples received by laboratories and a feedback mechanism to field personnel exists.

Status: Completed.

Findings: Currently being summarized for January 1994 report.

Future Action: Repeat survey in 3-5 years.

Comments: This is a companion activity to item A-20 under Processing Plant Activities.

APPENDIX A-9b
 FOOD SAFETY AND INSPECTION SERVICE
 SCIENCE AND TECHNOLOGY DIVISION
 INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Studies

Activity: Cow/Bull Survey -- Cows and bulls constitute 18 percent of beef animals slaughtered and are a major source of ground beef production. This survey will provide a microbiological "picture" or profile of cow and bull carcasses from Federally inspected plants. It will indicate whether certain pathogens are present and if so, at what level. This data will be used to document changes in the profile over time as inspection policies and procedures change, and will lead to further, more specialized studies that will evaluate specific products or the effect of specific decontamination intervention strategies. This study is supplementary to the Heifer/Steer study begun in 1992.

Start Date: 9/93

End Date: 10/94

Method of Reporting Final Results: Final report planned for December 1994.

Staff Years Expended or Required for Completion: 15.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$625,000

Evaluation Mechanisms In Place or Planned: Trial phase of 30-90 days to ensure sample collection techniques and analytical procedures are understood. Sample forms will be routinely reviewed for accuracy. System in place for determining acceptability of samples received by laboratories and feedback to field personnel as necessary.

Status: Underway

Findings: None yet available

Future Action: After 1 year of testing, data will be evaluated to determine interval between repetition of surveys.

APPENDIX A-9b (Cont.)

Comments: This is a companion activity to items A-20 under Processing Plant Activities.

APPENDIX A-9c
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Studies.

Activity: Broiler Chicken Survey -- Broiler chickens constitute approximately 93% of all poultry slaughtered. This survey will provide a microbiological "picture" or profile of broiler carcasses from Federally inspected plants. It will indicate whether certain pathogens are present and if so, at what level. This data will be used to document changes in the profile over time as inspection policies and procedures change, and will lead to further, more specialized studies that will evaluate specific products or the effect of specific decontamination intervention strategies.

Start Date: 12/93	End Date: 12/94	Method of Reporting Final Results: Final report planned for Winter 1995.
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Staff Years Expended or Required for Completion: 7.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$625,000

Evaluation Mechanisms In Place or Planned: Trial phase of 30-60 days to ensure sample collection techniques and analytical procedures are understood. Sample forms will be routinely reviewed for accuracy. System in place for determining acceptability of samples received by laboratories and feedback to field personnel as necessary.

Status: Protocol being developed to initiate survey.

Findings: None yet available

Future Action: After 1 year of testing, data will be evaluated to determine interval between repetition of surveys.

APPENDIX A-9c (Cont.)

Comments: This is a companion activity to items A-20 under Processing Plant Activities.

APPENDIX A-9d
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Service Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Studies

Activities: Turkey Survey -- This survey will provide a microbiological "picture" or profile of turkey carcasses from Federally inspected plants. It will indicate whether certain pathogens are present and if so, at what level. This data will be used to document changes in the profile over time as inspection policies and procedures change, and will lead to further, more specialized studies that will evaluate specific products or the effect of specific decontamination intervention strategies. This study complements baseline studies underway for steers/heifers, cows/bulls and broiler chickens.

Start Date: 8/94 **End Date:** 7/95 **Method of Reporting Final Results:** Final report planned for Fall 1995.

Staff Years Expended or Required for Completion: 7.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$625,000

Evaluation Mechanisms In Place or Planned: Trial phase of 30-90 days to ensure sample collection techniques and analytical procedures are understood. Sample forms will be routinely reviewed for accuracy. System in place for determining acceptability of samples received by laboratories and feedback to field personnel as necessary.

Status: Not yet started

Findings: None yet available

Future Action: After 1 year of testing, data will be evaluated to determine interval between repetition of surveys.

APPENDIX A-9d(Cont.)

Comments: This is a companion activity to items A-20 under Processing Plant Activities.

APPENDIX A-9c
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activity

Initiative: Microbiological Baseline Studies

Activity: Market Hog Survey -- This survey will provide a microbiological "picture" or profile of hog carcasses from Federally inspected plants. It will indicate whether certain pathogens are present and if so, at what level. This data will be used to document changes in the profile over time as inspection policies and procedures change, and will lead to further, more specialized studies that will evaluate specific products or the effect of specific decontamination intervention strategies. This study complements baseline studies underway for steers/heifers, cows/bulls, broiler chickens and turkeys.

Start Date: 3/94 **End Date:** 2/95 **Method of Reporting Final Results:** Final report planned for Spring 1995.

Staff Years Expended or Required for Completion: 15.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$625,000

Evaluation Mechanisms in Place or Planned: Trial phase of 30-90 days ensure sample collection techniques and analytical procedures are understood. Sample forms will be routinely reviewed for accuracy. System in place for determining acceptability of samples received by laboratories and feedback to field personnel as necessary.

Status: Not yet started.

Findings: None yet available.

Future Action: After 1 year of testing data will be evaluated to determine interval between repetition of surveys.

Comments: This is a companion activity to items A-20 under Processing Plant Activities.

APPENDIX A-9f
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Studies - follow up to Microbiological Baseline Program and Species Surveys

Activities: Targeted investigations (for example, head meat study, and specific product surveys.) -- These studies will provide information on the presence and level of selected microorganisms in various raw meat and poultry products at the time of manufacture. They are a follow up to the Microbiological Baseline studies. This is in-house research conducted in FSIS laboratories.

Start Date: 10/95

End Date: Ongoing

Method of Reporting Final Results: Data Analysis and Report

Staff Years Expended or Required for Completion: To be determined

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$800,000

Evaluation Mechanisms in Place and Planned: These types of studies are subject to laboratory quality control checks including sample integrity and routine screening of sample collection forms for accuracy.

Status: In planning stage.

Findings: None yet available

Future Action: Results of these investigations will be used to target further pathogen reduction efforts in high risk products. Data will be used to establish targets for reducing pathogens, plan future initiatives, support policy and procedure changes, and supplement risk analysis activities where specific data is applicable.

Comments: Estimated end dates and evaluation and reporting mechanisms are not completed at this time since the study protocols have not been developed

APPENDIX A-9g
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological Baseline Program

Activity: Use data to establish targets for reducing pathogens, plan future initiatives, support policy and procedure changes, and supplement risk analysis activities where specific data is applicable.

Start Date: 1/94 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: See A-9a through A-9f

Estimated Expenditures (including dates) or Appropriation Required for Completion: See A-9a through A-9g

Evaluation Mechanisms in Place or Planned: The use of microbiological data to modify, adjust or create policy and procedures will be subject to peer review and public comment.

Status: Several microbiological baseline surveys are underway or being planned. None is yet complete.

Findings: Not applicable

Future Action: Use microbiological data resulting from baseline studies to establish targets for reducing pathogens, plan future initiatives, support policy and procedure changes, and supplement risk analysis activities.

Comments: Baseline data which reveals low pathogen levels will be of limited use because of difficulty in demonstrating significant improvements when dealing with very low incidence. The usefulness of this information and its applicability will only be realized over a period of years January 24, 1994

APPENDIX A-10
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Disabled Cow Study

Activity: Microbiological Sampling of disabled cows -- This study researches the suspicion that a proliferation of or increased shedding of pathogenic organisms occurs when animals harboring these organisms in their intestines are severely stressed as may occur in disabled or "downer" animals. The results of this study will provide some insight into whether animals in a highly stressed state are a greater risk for pathogen shedding.

Start Date: 9/93 **End Date:** 6/94 **Method of Reporting Final Results:** Report findings and results; scheduled for Fall 1994.

Staff Years Expended or Required for Completion: 3.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: Study is under the control of a very few individuals because of its specialized nature. Microbiologic analyses conducted at contract laboratory is under review to determine whether necessary adjustments in procedures are needed.

Status: Underway

Findings: None to report at this time.

Future Action: Not applicable

APPENDIX A-10 (Cont.)

Comments: This study plans to gather information on 300 disabled animals and 300 "normal" cows. Due to the small sample population and need to coordinate sampling with presentation of disabled animals, this study will take through the Summer of 1994 to complete. Expenditures are based on shipping and laboratory supply costs.

APPENDIX A-11
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Microbiological sampling during pre-operational sanitation inspection

Activity: Incorporate microbiological sampling of equipment in conjunction with visual inspection into existing FSIS procedures for monitoring sanitation programs in meat and poultry plants.

Start Date: 11/93

End Date: 10/95

Method of Reporting Final Results: Microbiological test results will be recorded by FSIS in-plant personnel and submitted to a central collection point for analysis and evaluation.

Staff Years Expended or Required for Completion: Pre-trial pilot: 1 inspector per 10 plants sampling once per week. Expanded trial: 1 inspector per 100 plants sampling once per week. National implementation 1 inspector per 6500 plants sampling once per week. Pre-operational sanitation is routinely performed on inspector overtime.

Estimated Expenditures or Appropriations Required for Completion: \$3,487,000 for FY94 including cost of supplies, equipment, training, inspector time and travel, and analytical staff time. Cost for FY95 and thereafter \$1,544,000.

Evaluation Mechanisms in Place or Planned: Pre-trial in 10 plants to determine which of four commercially available tests kits is most effective and user friendly. Expanded trial to 100 plants will be reviewed by FSIS supervisory field personnel and Pathogen Reduction and microbiology staff. Protocol for analysis and evaluation of national data to be developed.

Status: Pre-trial in 10 plants underway. Began in 11/93 and scheduled for completion by 1/94.

Findings: None available at this time.

APPENDIX A-11 (Cont.)

Future Action: Design reporting program for results of micro-sampling in pre-operational sanitation; procure equipment; complete pilot; evaluate results; implement program nationwide.

Comments: This is a companion activity to item A-14f under Slaughter Plant Activities and item A-27c under Processing Plant Activities.

APPENDIX A-12
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Critical Control Point (CCP) Microbiologic Verification Testing

Activity: Beef Slaughter Process Control. Several critical control points associated with potential bacterial contamination are being sampled for overall bacterial counts to gather information on changes in contamination throughout the slaughter and dressing process.

Start Date: 11/93 **End Date:** 3/94 (projected) **Method of Reporting Final Results:** No decision yet on final report/timeframe.

Staff Years Expended or Required for Completion: 1.75

Estimated Expenditure or Appropriations Required for Completion: \$100,000

Evaluation Mechanisms in Place or Planned: Training of inspectors accomplished prior to initiation of study. Periodic reviews of laboratory forms, and oversight of program by headquarters slaughter inspection staff.

Status: Underway

Findings: Not available.

Future Action: These studies will provide information to support implementation of process control system in slaughter plants (HACCP), and familiarizes our inspection force with microbial monitoring methods.

Comments: This is a companion activity to item A-14a under Slaughter Plant Activities.

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Slaughter and Processing Research

Activity: Contract Research Studies -- Outside research needed to help answer questions regarding the characteristics of pathogenic bacteria, such as E. coli O157:H7. Research areas include questions about the risk factors for contamination during various phases, and under varying conditions, of slaughter and processing operations must also be answered. Questions must also be researched that provide answers regarding the most effective interventions to pursue to control pathogens during slaughter and processing.

Start Date: 10/94	End Date: Ongoing	Method of Reporting Final Results: Peer reviewed scientific publications/contractor reports.
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Staff Years Expended or Required for Completion: See comments.

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$1,000,000 -- FY 1994 funding will be used to identify needed research and the appropriate researchers to conduct investigations and to fund the research.

Evaluation Mechanisms in Place or Planned: Contract management methods.

Status: Research questions are currently being identified and prioritized.

Findings: Not available at this time.

Future Actions: Once needs are clarified, competitive bid proposals or competitive cooperative agreements will be announced in the "Commerce Business Daily" or the "Federal Register" seeking qualified contractors.

Comments: No definitive end dates since this is ongoing research. Since this is primarily contract research no substantial increase in staff years is contemplated

APPENDIX A-13b
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Slaughter and Processing Research

Activity: Beef Trimming vs. Washing Study -- Data from this study will be used to determine the relative efficacy of different decontamination techniques used in beef slaughter operations against pathogenic bacteria. This study may serve as support for changes in the handling of beef carcasses, if alternative techniques for removing contamination prove to be superior to trimming for pathogen control.

Start Date: 12/93 **End Date:** 12/94 **Method of Reporting Final Results:** Periodic updates and a final report by December 1994.

Staff Years Expended or Required for Completion: Contracted to Dr. Gary Acuff at Texas A&M University. Negligible FSIS staff years.

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$108,000

Status: Protocol agreed upon, study about to commence.

Findings: None yet available

Future Action: Not applicable

Comments:

APPENDIX A-14a
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: Develop a clean meat program to extend zero tolerance standard and promote prevention of fecal, ingesta, and milk contamination to all meat species.

Start Date: 5/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not Applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$10,000

Evaluation Mechanisms In Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system Feedback from on-site correlations in each plant during implementation.

Status: FSIS Directive 6420.1, Removal of Feces, Ingesta, and Milk Contamination from Meat Carcasses, submitted to inspectors' union for comment in October. Formal comment period is pending and the union has indicated possible invocation of impact and implementation bargaining.

Findings: None available at this time.

Future Action: Development of microbiological sampling portion. Upon implementation of directive, on-site correlations of all meat slaughter inspection personnel.

Comments: This is a companion activity to item A-12 under Slaughter Plant Activities.

APPENDIX A-14b
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: Develop a clean poultry program to extend zero tolerance standard for fecal and ingesta contamination to all poultry classes. The program would build in defect control for contamination by feces and ingesta; provide a zero tolerance test and require additional plant inspectors on-line if contamination were detected until process returned to zero contamination level. FSIS inspector verification of solution to problem(s) would be required.

Start Date: 6/93 **End Date:** Ongoing **Method of Report Final Results:** Not applicable

Staff Years expended or required for completion: .25

Estimated Expenditures or Appropriations Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system; feedback from on-site correlations in each plant during implementation. On-site correlations are in-plant training sessions designed to ensure that inspectors are uniformly and consistently enforcing regulations.

Status: Proposal for extending fecal and ingesta contamination to all poultry classes is under Departmental review.

Findings: None Available

Future Action:

Comments:

APPENDIX A-14c
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: Revise carcass Acceptable Quality Level (AQL) directive to remove fecal and ingesta contamination as defects under AQL system. Fecal and ingesta contamination will be handled per instructions in FSIS Directive 6420.1, and will result in automatic failure of product inspected.

Start Date: 5/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$10,000

Evaluation Mechanisms in Place and Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system.

Status: FSIS Directive 6420.2, Beef Carcass Acceptable Quality Levels Directive, submitted to inspectors union for comment in October. Formal comment period is pending and the union has indicated possible invocation of impact and implementation bargaining. This directive is part of the "Clean Meat Program."

Findings: Not applicable

Future Action: Not applicable

Comments:

APPENDIX A-14d
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter and processing procedures to assure reduction of pathogens.

Activity: Implement immediate actions on the cattle clean meat program in all beef slaughter plants.

Start Date: 11/93 **End Date:** Ongoing **Method of Reporting Final Results:**

Staff Years Expended or Required for Completion: 10

Estimated Expenditure or Appropriations Required for Completion: \$390,000

Evaluation Mechanisms in Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system; feedback from on-site correlations in each plant during implementation.

Status: Draft memorandum submitted to inspector's union for comment in November 1993. Final consultation with union December 8, 1993. Memorandum issued to field December 9, 1993. Planning meeting November 29 - December 1 to plan schedule of on-site visits to plants to provide direction to inspectors on uniform application of instructions.

Findings: None available

Future Action: On-site correlations for all cattle slaughter inspection personnel (beginning January 10, 1994).

Comments:

APPENDIX A-14e
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: Issue instructions to field inspectors and supervisors to reinforce mandatory trimming of all fecal, ingesta and milk contamination in beef slaughter operations. Additional instructions include enforcing zero tolerance for feces and ingesta or acceptable quality level (AQL) standards on carcasses and boneless beef.

Start Date: February 1, 1993	End Date: Ongoing	Method of Reporting Final Results: Memoranda of instructions to field inspectors and supervisors 2/1/93 and 3/2/93.
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Staff Years Expended or Required for Completion: 0.1

Estimated Expenditures (including dates) or Appropriation Required for Completion: No additional expenditures.

Evaluation Mechanisms In Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system

Status: The instructions provided in the interim guidelines are in effect until superseded by an FSIS Directive.

Findings: None available at this time.

Future Action: Follow-up of memo with efforts to ensure uniform application of instructions.

Comments:

APPENDIX A-14f
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activity

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: Implement a stronger pre-operational sanitation inspection program in meat slaughter plants by developing a formalized plan of inspection and by randomizing selection of equipment and facilities for inspection.

Start Date: 1987

End Date: Ongoing

Method of Reporting Final Results: Not applicable

Staff Years Expended or Required for Completion: 20

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$992,000

Evaluation Mechanisms in Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system.

Status: Two day training of in-plant veterinary medical officers and floor inspectors started 11/93. Development of the plan of inspection for each plant by the Inspectors-In-Charge and Circuit Supervisor's concurrence 11/93 - 1/94. Inspectors will be trained on-site before their rotation to performing preoperational sanitation. Revision of Directive 11,040.1 10/4/93.

Findings: Not applicable

Future Action: Preliminary implementation; February, 1994. Implementation date: March 1, 1994.

Comments:

APPENDIX A-14g
 FOOD SAFETY AND INSPECTION SERVICE
 SCIENCE AND TECHNOLOGY DIVISION
 INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: This activity is to revise the Sanitation Handbook used by inspection personnel, supervisors, and inspected plants. The handbook provides useful information and guidelines for proper sanitary operations during the production of meat and poultry products.

Start Date: 8/92 **End Date:** 4/94 **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: 5

Estimated Expenditures or Appropriations Required for Completion: \$250,000

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Revisions to the Sanitation Handbook were contracted out to GLH, Inc. beginning 08/30/92. Accelerated delivery of the product by the contractor was accomplished by 11/08/93. Internal review and comment on the Handbook by Agency offices and the inspectors' union was accomplished during November. Final edits for the Handbook are underway. Options for printing and distribution costs are being developed. Purchase order for printing and distribution is expected to be released in February, 1994. Receipt of the Handbook by field inspectors is expected by May, 1994.

Findings: Not applicable

Future Action: Not applicable

Comments: This is a companion activity to item A 27b under Processing Plant Activities.

APPENDIX A-15a
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Approved anti-microbial agents for use in slaughter plants as the science was developed to support such activities. Evaluated the effectiveness of organic acid rinses which reduce the bacterial load on carcasses during the slaughter process.

Activity: Published a directive that allows for the application of organic acids with instructions for monitoring to the FSIS inspectors. Directive "Pre-Evisceration Carcass Spray Systems" published November 24, 1992.

Start Date: 1/92 **End Date:** 11/92 **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: 0.10

Estimated Expenditures or Appropriations Required for Completion: \$4,000

Evaluation Mechanisms in Place or Planned: Literature review of all studies regarding the use of organic acids or other antimicrobial agents on meat - completed, but pending publication. Monitoring and evaluation of organic acid use included in the directive.

Status: The American Meat Institute petitioned FSIS to approve pre-evisceration carcass sprays. Data was presented and reviewed by the Agency. A literature search was also conducted. The data and literature supported the petition. The directive provides guidance to inspectors to ensure that the carcass spray procedure is followed. The use of pre-evisceration carcass sprays is voluntary; very few plants are using the procedure.

Findings: Results have demonstrated a slight reduction in pathogens on carcasses.

Future Action: This directive expands the Organic Acid Spray directive potentially to include other proven antimicrobial agents and allows for application of these antimicrobials at locations other than pre-evisceration provided sufficient scientific evidence is submitted to support such use.

APPENDIX A-15b
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Approved anti-microbial agents for use in slaughter plants as the science was developed to support such activities. Evaluated the effectiveness of organic acid rinses which reduce the bacterial load on carcasses during the slaughter process.

Activity: Published a directive allowing the use of Trisodium Phosphate (TSP) on poultry. Scientific data supports use as a safe, antimicrobial agent. FSIS Directive Number 6540.1 entitled "Use of Trisodium Phosphate as a Poultry Antimicrobial Agent," published 6/22/93.

Start Date: 1988 **End Date:** 6/93 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: .35

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$14,000.

Evaluation Mechanisms in Place or Planned: The data collected to support the use of TSP and results of pilot studies for this initiative are pending publication.

Status: A manufacturer petitioned FSIS for the post-chill use of TSP in poultry. In October 1992, FSIS granted interim approval, pending rulemaking, for the use of TSP on raw, post-chill poultry. Directive 6540.1 was issued in June, 1993 establishing conditions for the post-chill use of TSP in Federally inspected establishments. Pre-chill testing of TSP began in June, 1993. Results are still being reviewed. On January 5, 1994, FSIS published its proposed rule for the post-chill use of TSP in the Federal Register.

Findings: Data was provided that supported the effectiveness of TSP in reducing bacterial loads. Additional tests and pilot studies using trisodium phosphate continue to demonstrate new and more effective applications of this compound in slaughter plants.

APPENDIX A-15b

Future Action: New data submitted by a turkey slaughter plant and the manufacturer of TSP appear to support the use of TSP as a pre-chill carcass spray. The manufacturer has indicated that FSIS will be petitioned to approve TSP as a pre-chill carcass spray to reduce bacterial loads on poultry.

Comments:

APPENDIX A-16
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: To determine the feasibility of removing hair from cattle prior to slaughter to reduce potential bacterial contamination of meat and meat products.

Activity: Pilot tests and evaluation of the effectiveness and feasibility of dehairing cattle prior to slaughter, hide removal, and evisceration.

Start Date: 12/92 **End Date:** Experimental Pilot - 5/94 **Method of Reporting Final Results:** Report to be issued after pilot; publication of results subject to peer review.

Staff Years expended or required for completion: 0.25

Estimated Expenditures or Appropriations Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: Monitoring and data collection of pilot study to begin January 15, 1994.

Status: Equipment necessary for dehairing process was given a 90-day temporary experimental approval on December 8, 1993. Pilot testing to begin January 15, 1994, with 90-day test currently scheduled.

Findings: To be included in post-pilot report.

Future Action: Evaluate effectiveness and efficacy of dehairing process.

Comments:

APPENDIX A-17
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Enhance effective use of veterinary medical officers in plants that slaughter high-risk animals.

Activity: Examine current criteria used to classify veterinary assignments covering bovine slaughter plants.

Start Date: 3/93 **End Date:** 10/93 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: .10

Estimated Expenditure (including dates) or Appropriations Required for Completion: \$27,000

Evaluation Mechanisms in Place or Planned: Personnel Management Review Classification audits.

Status: FSIS reviewed veterinary staffing in high risk plants that slaughter cows, bulls and calves. One hundred twenty-four veterinary assignments at the GS-11 and GS-12 levels were reviewed. The review indicated some changes had occurred that placed additional demands and requirements on these types of veterinary assignments. The criteria were modified slightly, resulting in two upgrades. Two other assignments could also be upgraded using the existing criteria. Four in-service veterinarian positions upgraded 10/1/93

Findings: Not applicable.

Future Action: Some potential exists for additional upgrades based on significant levels of disease incidence encountered in the high risk plants.

Comments:

APPENDIX A-18
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Mandatory Hazard Analysis Critical Control Point (HACCP) Systems for Slaughter and Processing Plants

Activity: Hold roundtable discussion regarding HACCP. HACCP is a production control system designed to limit pathogenic contamination of poultry and meat at high-risk (critical) points in the production process. The roundtable is an opportunity to allow free and frank discussion of the concerns of all constituents prior to the issuance of a proposed regulation on HACCP. The meeting will assist FSIS through a thorough discussion of the issues and aid in drafting the rule for implementing a HACCP system of production in all meat and poultry plants.

Start Date: 2/94 **End Date:** Unknown **Method of Reporting Final Results:** Final Report, Spring 1994

Staff Years Expended or Required for Completion: 0.5

Estimated Expenditure or Appropriations Required for Completion: \$25,000

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Announcement in Federal Register

Findings: To be determined

Future Action: Hold roundtable meeting and publish findings/report.

Comments:

APPENDIX A-19
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Develop Rapid Microbiologic Methods for Laboratory or In-plant Use

Activity: Fund research in developing new and more rapid methods of identifying bacteria on or in various meat and poultry products. Newer methods are important for speeding laboratory results and are most useful in monitoring process control systems in slaughter and processing plants. Current methods used to detect pathogens in the food supply are often the DNA probes or ELISA (Enzyme Linked Immunoabsorbent Assay) screening tests followed by culture confirmation. This requires the growth of the pathogen (enrichment) on agar plates followed by biochemical identification. These methods require a minimum of 2-3 days to confirm results. Because of the large quantities of microorganisms needed for detection, this enrichment process represents a biological hazard which, at present, is too dangerous to be conducted in an in-plant environment.

Start Date: 10/94

End Date: To be determined

Methods of Reporting Final Results: Scientific publications

Staff Years expended or required for completion: 2.0

Estimated Expenditures or Appropriations Required for Completion: \$1,000,000

Evaluation Mechanisms in Place or Planned: Validation of the efficacy of rapid methods is conducted by multiple laboratories to ensure the accuracy, sensitivity, and repeatability of the method.

Status: Notice in the Federal Register was published outlining FSIS criteria for suitable rapid methods. Specific criteria include faster results; improved sensitivity, specificity, and accuracy; elimination of enrichment process, minimal biohazards, minimal hands-on technical time required, minimal technical competence to administer, minimal physical resources required to administer, and minimal cost per administration. Request published in the Commerce Business Daily (CBD) asking companies for information on new technologies and advancement in bacterial detection methods for process control. FSIS is currently identifying and prioritizing their needs for contract support to the Agency's internal method development activities.

Findings: Not available at this time.

APPENDIX A-19 (Cont.)

Future Action: Once needs are identified, competitive bid contracts or competitive cooperative agreements will be announced in the CBD or Federal Register.

Comments: No definitive end date since this is ongoing research.

APPENDIX A-20
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
INSPECTION OPERATIONS

Meat and Poultry Inspection Operations

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Microbiological Baseline Studies - follow up to Microbiological Baseline Program and Species Surveys

Activities: Ground Beef Survey -- This investigation will provide information on the prevalence of foodborne pathogens in ground beef produced under Federal inspection.

Start Date: 8/93 **End Date:** 2/94 **Method of Reporting Final Results:** Data Analysis and Report

Staff Years Expended or Required for Completion: 4.5

Estimated Expenditures (including dates) or Appropriation Required for Completion: \$145,000

Evaluation Mechanisms in Place and Planned: Sample collection forms are routinely screened by headquarters staff to ensure accuracy of information on sample. Study is a one-time survey requiring collection of a ground beef sample from 600 representative plants nationwide.

Status: Ongoing

Findings: None yet available

Future Action: Data will be compared with reported retail surveys. If necessary, survey will be conducted with a new population of ground beef plants.

Comments: This is a companion activity to items A-9a through A-9f and A-10 in Slaughter Plant Activities.

Pathogen Reduction Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Critical Control Point (CCP) Microbiological Verification Testing.

Activity: Ground Beef Patty Production. Several critical control points in the patty production process are being sampled for overall bacteria counts to determine the change in contamination throughout the process.

Start Date: 1/94 **End Date:** 4/94 **Method of Reporting Final Results:** Report expected for release in June, 1994.

Staff Years Expended or Required for Completion: 0.5

Estimated Expenditures of Appropriations Required for Completion: \$100,000

Evaluation Mechanisms In Place or Planned: Training of inspectors accomplished prior to initiation of study to test critical control points. Periodic review of laboratory sample request forms to ensure accuracy of information. Processing operations staff in headquarters to provide oversight to the field inspection staff.

Status: Trial phase being conducted to gather base bacteriologic data on beef patties at end of process.

Findings: No data available.

Future Action: Study concept to be extended to other ground meat and poultry products in FY 94 using appropriated resources. Data from these testing programs will provide information to support the implementation of process control systems for processed product operations (HACCP), and familiarize inspection staff with microbial monitoring techniques.

Comments: This is a companion project to item A-12 under Slaughter Plant Activities.

APPENDIX A-22b
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Mandate Safe-handling Instruction Labeling.

Activity: Achieved consensus with FDA on storage, handling and cooking parameters. All raw and partially-cooked meat and poultry products will include safe-handling instructions on their labels. This will apply to both inspected and uninspected processors.

Start Date: 2/93

End Date: 8/93

Method of Reporting Final Results: Resolution of storage, handling and cooking parameters.

Staff Years expended or required for completion: 0.1

Estimated Expenditures or Appropriations Required for Completion: Not applicable

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Completed

Findings: Not applicable

Future Action: Parameters incorporated into instructions..

Comments:

APPENDIX A-22a
FOOD SAFETY AND INSPECTION SERVICE
REGULATORY PROGRAMS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Safe-Handling Instruction Labeling.

Activity: All raw and partially-cooked meat and poultry products will include safe-handling instructions on their labels. This will apply to both inspected and uninspected processors and retail establishments. Conducted focus group research on effectiveness of alternative presentations of safe-handling instructions.

Start Date: 6/93 **End Date:** 8/93 **Method of Reporting Final Results:** Report of Research Triangle Institute.

Staff Years Expended or Required for Completion: 0.1

Estimated Expenditures of Appropriations Required for Completion: \$50,000

Evaluation Mechanisms In Place or Planned: Normal contract oversight.

Status: Completed.

Findings: Results were used in the development of the proposed safe handling instruction label.

Future Action: None needed; research used as basis for proposed rule.

Comments:

APPENDIX A-22c
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Mandate Safe-Handling Instruction Labeling.

Activity: Rulemaking. All raw and partially-cooked meat and poultry products will include safe-handling instruction on their labels. This will apply to both inspected and uninspected processors and retail establishments. A copy of the new label follows this page.

Start Date: 2/93

End Date: 2/94

Method of Reporting Final Results: Publication of Final Rule in Federal Register.

Staff Years Expended or Required for Completion: 1.5

Estimated Expenditures of Appropriations Required for Completion: \$21,250

Evaluation Mechanisms In Place or Planned: Implement and enforce final rule.

Status: An interim rule was published on 8/16/93. A final rule was published 10/12/93. On 11/3/93, these actions were rescinded and a proposed rule was published. Comments on the proposal were accepted through 12/20/93.

Findings: Not applicable

Future Action: Implementation of a final rule (3/94).

Comments:

**Label as described in Code of Federal Regulations,
title 9, parts 317 and 381.**

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.



Keep refrigerated or frozen.
Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods.
Wash working surfaces (including cutting boards),
utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers
immediately or discard.

Actual size

Safe Handling Instructions

This product was prepared from inspected and passed meat and/or poultry. Some food products may contain bacteria that could cause illness if the product is mishandled or cooked improperly. For your protection, follow these safe handling instructions.



Keep refrigerated or frozen.
Thaw in refrigerator or microwave.



Keep raw meat and poultry separate from other foods.
Wash working surfaces (including cutting boards),
utensils, and hands after touching raw meat or poultry.



Cook thoroughly.



Keep hot foods hot. Refrigerate leftovers
immediately or discard.

Enlarged

APPENDIX A-23a
 FOOD SAFETY AND INSPECTION SERVICE
 SCIENCE AND TECHNOLOGY DIVISION
 REGULATORY PROGRAMS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Cooked Pattie Docket

Activity: Issue regulations specifying heat processing, cooling, handling, labeling and storage requirements for certain uncured meat products such as hamburgers, salisbury steaks and beef patties processed in federally inspected plants. The regulation provides the processing requirements necessary to kill pathogens.

Start Date: 1/93

End Date: 8/93

Method of Reporting Final Results: Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditure or Appropriations Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: In-plant Inspection

Status: Regulation completed

Findings: Regulation being enforced by FSIS inspectors.

Future Action: Verify compliance using microbiological sampling

Comments:

APPENDIX A-23b
**FOOD SAFETY AND INSPECTION SERVICE
 INSPECTION OPERATIONS**

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Cooked Pattie Docket

Activity: Issue directives to inspection personnel identifying tasks and inspection methods and procedures to enforce regulations.

Start Date: 1/93 **End Date:** 9/93 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditure or Appropriations Required for Completion: \$60,000

Evaluation Mechanisms in Place or Planned: Supervisory reviews and analysis of results of inspection tasks.

Status: Directives issued

Findings: Proper enforcement in place.

Future Action: Monitor process procedures using temperature probes.

Comments:

APPENDIX A-24
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Mandate recordkeeping in inspected plants to support traceback capability.

Activity: This initiative complements the animal identification initiative so that more complete traceback can be accomplished. These regulations will require inspected plants to maintain sufficient records to allow lots of finished products to be traced to specific meat and non-meat ingredients.

Start Date: 3/93 **End Date:** Spring, 1994 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures of Appropriations Required for Completion: \$10,000

Evaluation Mechanisms In Place or Planned: In-plant inspector will monitor plants' records for completeness and accuracy.

Status: Proposed Regulation is in final Department clearance.

Findings: Not applicable

Future Action: Comment analysis and publication of a final rule; implementation of final rule.

Comments: This is a companion activity to item A-8 under Slaughter Plant Activities and A-6 under Live Animal Activities.

APPENDIX A-25
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION
Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Irradiation Petition

Activity: The Agency is considering the submission of a Food Additive Petition (FAP) to FDA permitting irradiation of raw beef products. The irradiation of beef products would provide an assurance that significant foodborne pathogens will be destroyed in raw products.

Start Date: 1/94 **End Date:** To be determined **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: None

Estimated Expenditures or Appropriations Required for Completion: \$150,000

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Under Departmental review.

Findings: Not applicable

Future Action: Determination whether action should be considered relative to FAP. Approval of the FAP and publication in the Federal Register.

Comments:

APPENDIX A-26
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Control Bacteria in Ground Meat and Meat Trimmings.

Activity: Establish time and temperature requirements to reduce bacteria proliferation in ground meat and meat trimmings.

Start Date: 5/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: 2.0

Estimated Expenditures or Appropriations Required for Completion: \$80,000

Evaluation Mechanisms in Place or Planned: In-plant inspector will monitor process controls (cooler temperature, carcass spacing, humidity) and verify carcass and meat temperatures with temperature probes.

Status: Completed scientific literature review; 9/8 consultations with Agricultural Research Service, Micro Food Safety Research Unit; various consultations with food scientists and microbiologists; currently drafting proposed rule.

Findings: Carcasses and meat products should be maintained at 40° F.

Future Action: Verify compliance using microbiological sampling.

Comments:

APPENDIX A-27a
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Strengthen current processing procedures to assure reduction of pathogens.

Activity: Revise FSIS Boneless Meat Reinspection Directive 7320.2 to make fecal and ingesta contamination an automatic failure under the boneless beef reinspection procedure. This directive is included as part of the "Clean Meat Program."

Start Date: 5/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 1.25

Estimated Expenditure or Appropriations Required for Completion: \$10,000

Evaluation Mechanisms in Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA) system.

Status: Directive submitted to inspectors' union for comment in October. Formal comment period is pending and the union has indicated possible invocation of impact and implementation bargaining.

Findings: Not applicable

Future Action: Not applicable

Comments: Currently, as per Agency memo dated March 2, 1993, any fecal or ingesta contamination found on the boneless reinspection results in an automatic failure. This is a companion activity to items A-14b through A-14e under Slaughter Plant Activities.

APPENDIX A-27b
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Strengthen current slaughter procedures to assure reduction of pathogens.

Activity: This activity is to revise the Sanitation Handbook used by inspection personnel, supervisors, and inspected plants. The handbook provides useful information and guidelines for proper sanitary operations during the production of meat and poultry products.

Start Date: 8/92 **End Date:** 4/94 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 5.0

Estimated Expenditure or Appropriations Required for Completion: \$250,000

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Revisions to the Sanitation Handbook were contracted out to GLH, Inc. beginning 08/30/92. Accelerated delivery of the product by the contractor was accomplished by 11/08/93. Internal review and comment on the Handbook by Agency offices and the inspectors' union was accomplished during November. Final edits for the Handbook are underway. Options for printing and distribution costs are being developed. Purchase order for printing and distribution is expected to be released in February, 1994. Receipt of the Handbook by field inspectors is expected by May, 1994.

Findings: Not applicable

Future Action: See "status" above.

Comments: This is a companion activity to A-14g under Slaughter Plant Activities.

APPENDIX A-27c
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Processing Plant Activities

Initiative: Strengthen current processing procedures to assure reduction of pathogens.

Activity: Devise uniform pre-operational sanitation inspection program for all processing plants.

Start Date: 4/94 **End Date:** 3/95 **Method of Reporting Final Results:** FSIS Directive

Staff Years expended or required for completion: 20.0

Estimated Expenditures or Appropriations Required for Completion: Covered under normal Agency operation costs.

Evaluation Mechanisms in Place or Planned: Monthly supervisory visits; use of Progressive Enforcement Action (PEA)

Status:

Findings: Not applicable

Future Action: Future implementation (3/94) of pre-operational sanitation program in meat slaughter plants, the comparable program for use in processing plants will be designed. Design of the program in processing will be more complex than slaughter, because of the variety of processes used to make processed products.

Comments: This is a companion activity to A-14f under Slaughter Plant Activities.

APPENDIX A-28
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service and Retail Activities

Initiative: Sponsor teleconference

Activity: Cooperate with FDA to produce teleconferences on food safety topics for State and local health officials

Start Date: 3/93 **End Date:** To be determined **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 1.5

Estimated Expenditures/Appropriation Required for Completion: \$50,000

Evaluation Mechanisms in Place or Planned: Schedules for planning and holding teleconference submitted and monitored

Status: Teleconference held 9/2/93 featuring speakers from FSIS, FDA, and two State health departments

Findings: Not applicable

Future Action: In 1994, co-sponsor two teleconferences on Proper Storage and Preparation of Raw and Undercooked Foods and on the new Food Code. In 1995, if needed, co-sponsor additional teleconferences on food safety topics.

Comments:

APPENDIX A-29a
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service And Retail Activities

Initiative: Assist State Enforcement programs.

Activity: Achieve consensus with FDA on storage, and handling and cooking parameters. Provide technical and resource assistance to states to carry out their enforcement efforts in food service and retail establishments. Cooperate in developing and supporting model food codes to provide uniform technical guidance for cooking and handling.

Start Date: 2/93 **End Date:** 8/93 **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: 0.25

Estimated Expenditures or Appropriations Required for Completion: No additional expenditures.

Evaluation Mechanisms in Place or Planned: Evaluation by FDA

Status: Completed

Findings:

Future Action: FDA publication of Notice of Availability of the Food Code, incorporating consensus items. Teleconference for State and local public health authorities.

Comments:

APPENDIX A-29b
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service and Retail Activities

Initiative: Assist State Enforcement Programs

Activity: Produce a video tape for state and local health officials demonstrating the proper method to analyze meat and poultry samples for E. coli.

Start Date: 8/93 End Date: 2/94 Method of Reporting Final Results: Not applicable

Staff Years Expended or Required for Completion: 1.0

Estimated Expenditures/Appropriation Required for Completion: \$15,000

Evaluation Mechanisms in Place or Planned: Schedule for completion submitted and monitored

Status: Taping completed.

Findings: Not applicable

Future Action: 1/94: Complete editing and final production. 2/94: Distribute videotape to State public health departments, State agriculture departments, and trade groups.

Comments:

APPENDIX A-30
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service and Retail Activities

Initiative: Educate Fast Food Chain and Restaurant Employees

Activity: Cooperate with USDA Extension Service and trade organizations to increase awareness of safe food handling among fast food chain and restaurant employees.

Start Date: 1992 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.5

Estimated Expenditures/Appropriation Required for Completion: \$150,000

Evaluation Mechanisms in Place or Planned: Schedules submitted and monitored.

Status: Educational packet from FSIS and FDA targeted to 9,000 fast food and restaurant outlets in final clearance. Negotiations underway with Extension Service and National Restaurant Association on cooperative educational effort. Sponsored exhibits at National Restaurant Association Show, Southeast Hospitality and Food Service Show, and International Hotel/Motel and Restaurant Show in 1993.

Future Action: 1/94: Meet with Food Safety Council of National Council of Chain Restaurants to discuss joint initiatives. 5/94: Sponsor exhibit at National Restaurant Association Show to promote "Food Safety is No Mystery" and food safety education initiatives. 6/94: Finalize joint initiatives with National Restaurant Association and National Council of Chain Restaurants to promote food safety education for restaurant employees.

APPENDIX A-31a
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service and Retail Activities

Initiative: Educate food handlers in institutions serving at-risk populations.

Activity: Coordinate with the HHS Office on Aging to develop and distribute food safety education materials to food preparers serving senior citizens.

Start Date: 9/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures/Appropriation Required for Completion: \$50,000

Evaluation Mechanisms in Place or Planned: Schedules submitted and monitored.

Status: Cooperated with National Association of Nutrition and Aging Service Providers and the Administration on Aging to Nutrition Coordinators to promote food safety education at national meetings. Cooperated with Administration on Aging to incorporate questions on food safety and sanitation in nutritional survey of providers of local feeding programs.

Findings: Not applicable

Future Action: 3/94: Sponsor exhibits at American Society of Aging Convention to promote food safety education to food service providers and health care administrators. 3/94: Distribute package of food safety information to Area Offices on Aging. 1995: Use data from AOA survey to develop educational material targeted to senior centers and home meals programs.

Comments:

APPENDIX A-31b
 FOOD SAFETY AND INSPECTION SERVICE
 INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Food Service and Retail Activities

Initiative: Educate food handlers in institutions serving at-risk populations.

Activity: Produce and distribute food safety education materials for day care centers and schools

Start Date: 9/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures/Appropriation Required for Completion: \$225,000

Evaluation Mechanisms in Place or Planned: Schedules submitted and monitored.

Status: Cooperated with FNS Child and Adult Care Food Program to integrate food safety information in new recipe cards being developed for Feeding Program managers and to incorporate food safety information in new management training program.

Findings: Preliminary assessment completed indicating a need for food safety training programs for day care providers.

Future Action: 1/94: Determine means of distributing to day care training programs. 3/94: Distribute food safety education package (posters, print materials, video tape) to State agencies that provide training for food service preparers in FNS feeding programs. 7/94: Sponsor exhibit at American School Food Service Association Convention to promote food safety education. 9/95: Distribute day care training package.

Comments:

APPENDIX A-32a
 FOOD SAFETY AND INSPECTION SERVICE
 INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Intensify consumer awareness of Safe Food Handling Practices.

Activity: Improve understanding of the risks involved in unsafe food handling practices and provide practical food safety advice for consumers.

Start Date: 1/93 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.25

Estimated Expenditures/Appropriation Required for Completion: \$50,000

Evaluation Mechanisms in Place or Planned: Plans submitted and monitored.

Status: Promoted media appearances for Meat and Poultry Hotline home economists resulting in hundreds of radio interviews, magazine interviews, and appearances on CBS Morning Show, and Live with Regis and Kathie Lee. Cooperated with Food Marketing Institute, American Meat Institute and National Livestock and Meat Board, Extension Service and FDA to produce and distribute brochure to consumers on safe handling of ground meat and poultry.

Findings: Not applicable

Future Action: 1994: Exhibit at conventions promoting food safety education for consumers; Book and the Cook; American Home Economics Association; American Association of Retired Persons. 1994: Media tours by Meat and Poultry Hotline Director to major magazines and national television shows to promote safe food handling. Ongoing: Produce and release video news releases on seasonal food safety topics.

Comments:

APPENDIX A-32b
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Intensify Consumer Awareness of Safe Food Handling

Activity: Conduct a public awareness campaign in conjunction with implementation of safe food handling labels

Start Date: 1994 **End Date:** Ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.75

Estimated Expenditures/Appropriation Required for Completion: \$150,000

Evaluation Mechanisms in Place or Planned: Plans submitted and monitored.

Status: Brochure, video news releases, and public service announcements have been produced or are in production.

Future Action: Early 1994: In conjunction with implementation of safe handling regulation: Release print and radio public service announcements. Promote interviews with Secretary, Assistant Secretary and other USDA officials. Send label information electronically through Extension Service electronic network to State and country Extension agents for dissemination to consumers. Promote food safety and safe handling message at conventions. Involve consumers in securing compliance by establishing call-in point in FSIS.

Comments: Starting date dependent on final regulation.

APPENDIX A-33a
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Expand food safety education to at-risk populations

Activity: Produce a video tape on safe food handling targeted to pregnant women and mothers with small children (Women, Infants and Children Program participants and others).

Start Date: 1/94 End Date: 1/95 Method of Reporting Final Results: Not applicable

Staff Years Expended or Required for Completion: 0.75

Estimated Expenditures/Appropriation Required for Completion: \$75,000

Evaluation Mechanisms in Place or Planned: Plans submitted and monitored.

Status: Preliminary needs assessment completed in cooperation with FNS.

Findings: Not Applicable

Future Action: 1995 -- Distribute Video

Comments:

APPENDIX A-33b
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Expand food safety education to at-risk populations

Activity: Develop a food safety education program targeted to parents of children aged 4-10. This age group has suffered the most illnesses caused by the pathogen *E. coli* 0157:H7. The program urges parents to teach their children about eating only thoroughly cooked hamburgers.

Start Date: 6/94 **End Date:** Ongoing **Method of Reporting Final Results:** Distribution of material

Staff Years Expended or Required for Completion: 0.75

Estimated Expenditures/Appropriation Required for Completion: \$300,000

Evaluation Mechanisms in Place or Planned: Schedule for planning and development is submitted and monitored.

Status: Plan drafted identifying audience, needs, and potential delivery methods.

Findings: Not applicable

Future Action: 1994: Research and finalize plan; 1995: Launch initiative.

Comments:

APPENDIX A-34
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Promote Materials

Activity: Work with Extension agents, industry groups, academic institutions, and consumer and health groups to promote existing and new consumer education materials on food safety.

Start Date: 3/93 **End Date:** 9/95 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 0.5

Estimated Expenditures/Appropriation Required for Completion: \$100,000

Evaluation Mechanisms in Place or Planned: Schedule for planning and development is submitted and monitored.

Status: Special edition of Food News for Consumers on E. coli sent to 1,500 food editors and 1,800 Extension Service specialists; Distributed 250,000 food safety publications; Cooperated with Consumer Information Center to distribute 65,000 copies of "Quick Consumer Guide to Safe Food Handling."

Findings: Not applicable

Future Action: Continue and enhance promotion efforts through exhibits at relevant conventions and through the Extension Service. Continue liaison with Consumer Information Center.

Comments:

APPENDIX A-35
FOOD SAFETY AND INSPECTION SERVICE
INFORMATION AND LEGISLATIVE AFFAIRS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Consumer Awareness

Initiative: Apply Hazard Analysis Critical Control Point (HACCP) approach to food safety education; develop consumer and educator materials.

Activity: Identify consumers as one control point in farm to table food safety continuum. Published "Margin of Safety" project report, "A Quick Consumer Guide to Safe Food Handling", and "Preventing Foodborne Illness" for Extension agents, local public health, and other food safety educators.

Start Date: 1988 **End Date:** Ongoing

Method of Reporting Final Results: Distribution of 1989 project report and publications still in use.

Staff Years Expended or Required for Completion: 3.0

Estimated Expenditure or Appropriations Required for Completion: \$120,000

Evaluation Mechanisms in Place or Planned: An FSIS-Extension Service working group on food safety education reviews each other's projects on an ongoing basis, to seek areas of cooperation in education and public service.

Status: Completed. Being used as prototype for other food safety education programs targeted to at-risk groups.

Findings: Not applicable

Future Action: Based on user comments will plan format revision of consumer publication in order to enable easier photocopying.

Comments:

APPENDIX A-36
 FOOD SAFETY AND INSPECTION SERVICE
 POLICY EVALUATION AND PLANNING STAFF

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Develop the meat and poultry regulatory program of the future (Track II.)

Activity: Design a new, risk-based, farm-to-table regulatory program for meat and poultry production.

Phase I establishes the working structure, regulatory framework, and the process for designing the future meat and poultry regulatory system.

Phase II addresses the technical, developmental, and research issues associated with establishing hazards and controls throughout the meat and poultry chain of production.

Phase III addresses the design of components of the new system based on information generated in Phase I.

Phase IV will develop individual components of new system and methods for testing and evaluation.

Start Date: 1/93 **End Date:** 8/95 **Method of Reporting Final Results:** Final Report, late 1995

Staff Years Expended or Required for Completion: 8.0

Estimated Expenditure or Appropriations Required for Completion: The work of Technical Analysis Groups in Phases II and III will cost approximately \$2.5 million over the next two years, primarily for travel and per diem expenses. This figure assumes about 150 participants.

Evaluation Mechanisms in Place or Planned: Methods will be developed to evaluate proposed programs and procedures as part of Phase IV.

Status: Implementation will proceed in four phases. Phase I has been completed. It established the working structure, regulatory framework principles, and development process for the future program. Phase II is underway.

Findings: Not applicable.

Future Action: Phases II-IV

Comments: The final report will propose subjects for further exploration through field testing and/or research and development. Cost estimates cannot be provided for these activities now.

APPENDIX A-37
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF THE ADMINISTRATOR

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Form a public health division within FSIS and hire a public health advisor.

Activity: Public health physician will head a new FSIS public health division that works closely with other public health agencies, such as FDA, and CDC, to incorporate human health concerns into the food safety program.

Start Date: 2/93 **End Date:** 1/94 **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 1.0

Estimated Expenditure or Appropriations Required for Completion: \$150,000 per year.

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Interviews with candidates began January, 1994.

Findings: Not applicable.

Future Action: Detail public health physician to FSIS; create Division of Public Health.

Comments:

APPENDIX A-38
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF THE ADMINISTRATOR

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Creation of Centers for Disease Control (CDC) liaison position.

Activity: Liaison officer will assist CDC in the investigation of foodborne outbreaks and help to integrate food safety issues related to meat and poultry into planning and day-to-day operations at CDC.

Start Date: 12/93 **End Date:** ongoing **Method of Reporting Final Results:** Not applicable

Staff Years Expended or Required for Completion: 1.0 Indefinite

Estimated Expenditure or Appropriations Required for Completion: Approximately \$66,609 per year.

Evaluation Mechanisms in Place or Planned: Not applicable

Status: CDC liaison will begin work in early February, 1994.

Findings: Not applicable

Future Action: Not applicable

Comments:

APPENDIX A-39
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Expand research authorities within USDA.

Activity: Published regulation permitting USDA Agencies other than Agricultural Research Service to contract for research. FSIS currently lacks research authority and must contract with ARS or outside sources, such as universities, to conduct food safety research.

Start Date: 8/93 **End Date:** Ongoing **Method of Reporting Final Results:** Secure delegated authority

Staff Years expended or required for completion: .10

Estimated Expenditures or Appropriations Required for Completion: No additional expenditures

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Rule published August 12, 1993

Findings: Not applicable

Future Action: Not applicable

Comments:

APPENDIX A-40
FOOD SAFETY AND INSPECTION SERVICE
OFFICE OF THE ADMINISTRATOR

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Creation of a Pathogen Reduction Task Force

Activity: Form an interagency task force to coordinate and address research and regulatory needs and assist with future prevention activities. Task force will be responsible for leadership, coordination and oversight in Department's efforts to reduce pathogens in meat and poultry.

Start Date: 12/93

End Date: On-going

Method of Reporting Final Results: Not applicable

Staff Years expended or required for completion:

Estimated Expenditures or Appropriations Required for Completion: Covered under normal Agency operating costs.

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Secretary designated the Acting Assistant Secretary, Marketing and Inspection Services, Patricia Jensen to lead the task force. Task force members will include representatives of other USDA Agencies, other Federal agencies and interested parties.

Findings: Not applicable

Future Action: Not applicable

Comments:

APPENDIX A-41
FOOD SAFETY AND INSPECTION SERVICE
INSPECTION OPERATIONS

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Federal Government Process

Initiative: Increase in-plant inspection staff (160 in FY 1993 and 40 for FY 1994)

Activity: This activity is to reduce the number of inspection vacancies in Federally-inspected plants by hiring more staff.

Start Date: 3/93 **End Date:** 9/93 **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: Not applicable

Estimated Expenditures or Appropriations Required for Completion:

\$ 4 million in FY 1993 - to hire 160 additional inspectors

\$10 million in FY 1994 - annualization of salary costs for the 160 and full funding for 40 inspectors for FY94

Evaluation Mechanisms in Place or Planned:

Status: Increased employment of in-plant inspection personnel was completed by the end of FY 1993. Of the net 200 increase, 160 were on-board by early May, 1993 and the remaining 40 were employed by the end of September, 1993.

Findings: Not applicable

Future Action: Not applicable

Comments:

APPENDIX A-42
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE
Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish capability for independent review and assessment of program operations.

Activity: Establish Review and Assessment (R&A) program in FSIS. R&A will assist FSIS enforcement efforts through various review programs and tracking mechanisms. The office will assist the Administrator in investigating allegations of program breakdowns or other matters that could compromise the effectiveness of the inspection system in protecting public health.

Start Date: 7/93 **End Date:** Spring, 1994 **Method of Reporting Final Results:** Annual Accomplishment Report of Deputy Administrator.

Staff Years Expended or Required for Completion: 45.0 (proposed)

Estimated Expenditures (including dates) or Appropriation Required for Completion: Annual Estimated Salary and Benefits = \$2,560,000. Remainder of budget under development due to Agency reorganization plan.

Evaluation Mechanisms in Place or Planned: Degree to which recommendations are accepted/adopted will reflect effectiveness of R&A.

Status: Five full-time permanent employees in place; 32 employees detailed to R&A pending approval of FSIS reorganization. Consultation with employee organizations completed October, 1993. Approval and implementation expected Spring, 1994.

Findings: Not applicable

Future Action: Upon approval of reorganization, fill vacancies to bring R&A to full staffing. Further development of R&A programs and systems depends on approval of reorganization and staffing of R&A positions.

Comments:

APPENDIX A-43a
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish an internal assessment function in FSIS

Activity: Conduct investigations of alleged program breakdowns. The complaints and allegations addressed originate from a variety of sources including employees, management officials, whistleblowers, Office of the Inspector General, meat and poultry plant management, consumers, and others.

Start Date: 7/93 **End Date:** Ongoing **Method of Reporting Final Results:** Report of findings and recommendations to the Administrator on a case-by-case basis.

Staff Years Expended or Required for Completion: 6.2

Estimated Expenditures (including dates) or Appropriation Required for Completion: Estimated Annual Salaries and Benefits: \$ 356,000. Remainder of budget under development; this is a new unit.

Evaluation Mechanisms in Place or Planned: Tracking systems will measure the extent to which recommendations are adopted. Plant profile system planned for future will measure extent to which assessments are targeting problem plants.

Status: This activity has been implemented as of November, 1993. Approximately 30 inquiries under review. Complaint Tracking System established to assure appropriate inquiries and corrections are made, and to allow for trend analysis.

Findings: Individual program assessment findings vary widely. Initial reports indicate that this new activity will permit accelerated enforcement activity at meat and poultry plants, and/or issuance of revised or clarified policies on inspection, and stronger program management.

Future Action: Develop Recommendations Tracking System in FY 1994. Develop prevention-oriented quality assessment and internal management review capabilities in future fiscal year.

Comments:

APPENDIX A-43b
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish an internal assessment capability in FSIS

Activity: Track complaints and referrals. The purpose of the Complaint Tracking System is to track complaints and allegations about FSIS program operations from a variety of internal and external sources, to ensure they are addressed and corrective action is taken. The Recommendations Tracking System is intended to identify and track recommendations generated by audits and reviews conducted within and outside the Agency, to ensure they are acted upon. Both systems will also be used to direct the Agency's attention to problem areas which recur in the context of complaints and/or review results reported in the systems.

Start Date: July, 93 **End Date:** Ongoing **Method of Reporting Final Results:** Automated reports on a quarterly or ad-hoc basis. Analytical reports on a semi-annual basis.

Staff Years Expended or Required for Completion: 2.0

Estimated Expenditures (including dates) or Appropriation Required for Completion: Estimated Salary and Benefits for Completion: \$ 82,000 (Ongoing: \$ 59,000 per year). Additional costs minimal; plan to use existing hardware and software for tracking systems.

Evaluation Mechanisms in Place or Planned: Post-implementation evaluation of Complaint Tracking System by users early 1994. Post-implementation evaluation of Recommendations Tracking System planned for 6 months after its implementation.

Status: Complaint tracking system developed September, 1993. Management analyst hired to work on development and enhancement of tracking systems. for internal assessment.

Findings: Not applicable

Future Action: Tracking System development began January, 1994 with completion expected October, 1994.

Comments:

APPENDIX A-43c
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE
Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish an internal assessment capability in FSIS

Activity: Conduct in-depth special project reviews. Special project reviews are in-depth reviews of specialized segments of program operations. The reviews include consultation with front-line supervisors and inspection workforce to solicit suggestions for improvement to program operations.

Start Date: 7/93 **End Date:** Ongoing **Method of Reporting Final Results:** Final special project reports to the Administrator

Staff Years expended or required for completion: 10.0

Estimated Expenditures or Appropriations Required for Completion: Estimated Annual Salary and Benefits: \$596,000. Estimated Travel Expenses: \$ 75,000. Remainder of budget under development.

Evaluation Mechanisms in Place or Planned: The extent to which recommendations are accepted and adopted will reflect the effectiveness of these reviews.

Status: New program

Findings: None yet available

Future Action: Plan to conduct at least two special reviews each year, based on Agency concerns. Future plans include systematically scheduling post-implementation reviews of program innovations/new inspection systems

Comments:

APPENDIX A-44
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish a new plant review, followup and reporting system to focus on priority public health and food safety issues.

Activity: Review 1,000 Federally inspected meat and poultry plants, including approximately 650 with history of non-compliance. Plant reviews are unannounced and focus on priority public health concerns. Results are referred for immediate corrective action, and enforcement measures taken against seriously non-compliant plants. Plants selected for review include a group targeted for review due to historical non-compliance, and a control group of plants.

Start Date: 7/93	End Date: 9/95	Method of Reporting Final Results: Individual plant reports Quarterly Reports to Administrator, March, 1994
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Staff Years Expended or Required for Completion: 24.0

Estimated Expenditures (including dates) or Appropriation Required for Completion: Estimated Salary and Benefits per 1,000 reviews: \$1,400,000. Estimated Travel Expenses per 1,000 reviews: \$700,000

Evaluation Mechanisms in Place or Planned: Followup reviews within 6 months for plants found to be seriously deficient upon initial review. Reassessment of revised plant review methodology planned for March, 1994.

Status: Revision of plant review methodology completed September, 1993. 79 plant reviews conducted in September, 1993 using new methodology. Additional plant reviews underway as of December, 1993.

Findings: Of the 79 plants reviewed in September 1993, 21 were issued Accelerated Deficiency Notices indicating serious loss of process control.

Future Action: Develop plan for using review information to provide "early warning" of needed program improvements, and for better assessing plant capabilities for managing critical control points. Explore enhancements to plant review system such as incorporating scientific tests or processes into methodology.

APPENDIX A-45
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Establish capability for identifying and predicting non-compliant meat and poultry plants.

Activity: Develop a profile of non-compliant plants. Proposed profile system would identify establishments that are, or may become, non-compliant and require additional FSIS oversight. Timeframes and specific costs associated with this effort are highly uncertain as this activity is in the conceptual stage, and a full development effort depends on results of a feasibility study and what experience with other assessment activities reveals about the need for this profile system. In the meantime, will improve use of the existing Review and Evaluation Information System to identify problem plants and positive and negative trends in plant compliance.

Start Date: 7/93 **End Date:** 12/95

Method of Reporting Final Results: Feasibility study report, Spring, 1995
Final report on system, December, 1995

Staff Years expended or required for completion: Estimate 1 staff year for Feasibility Study; 2.5 staff years for Development Effort

Estimated Expenditures or Appropriations Required for Completion: \$58,000 (Feasibility Study); \$145,000 (Development Effort)

Evaluation Mechanisms in Place or Planned: Six months to one year after implementation, evaluation of profile versus actual plant compliance would be conducted.

Status: Conceptual proposal for plant profile system developed August, 1993.

Findings: Not yet available.

Future Action: Begin feasibility study - Fall, 1994. If feasible, develop plant profile system - Spring, 1995

Comments:

APPENDIX A-46
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Determine source and incidence of *E. coli* 0157:H57

Activity: Conduct reviews of plants involved in supply and production of beef for hamburger patties. In September, 1993, unannounced followup reviews were conducted in the 20 plants found to have serious process control problems. The 90 plant reviews were ordered by Secretary Espy, in response to the outbreak of *E. coli* 0157:H57 in the Northwestern U.S.

Start Date: 3/93 **End Date:** 5/93 **Method of Reporting Final Results:** Individual plant reports

Staff Years Expended or Required for Completion: Approximately 2.0

Estimated Expenditures (including dates) or Appropriation Required for Completion: Approximate Salary and Benefits Expended (March - May, 1993): \$ 110,000. Approximate Travel Expenditures (March - May, 1993): \$ 55,000

Evaluation Mechanisms in Place or Planned:

Status: 90 plants were reviewed during March-May. Follow-up reviews conducted on 20 of these plants in September.

Findings: 52 of the 90 plants had one or more conditions requiring corrective action, some of which involved temporary shutdown. Twelve of these plants were placed under heightened levels of inspection after a second review (during the March-May timeframe) found conditions were still unacceptable. In all, 20 plants were found to have serious process control problems. These 20 plants were reviewed again in September. Of these, 6 plants were still operating with a serious loss of process control and were issued Accelerated Deficiency Notices (ADN's).

Future Action: Inspection Operations will ensure that corrective actions are taken to bring into compliance the 6 plants issued ADN's. Current and future plant reviews will target plants with history of non-compliance. In addition, reviews will continue to be unannounced and focus on priority public health concerns. Special reviews will be conducted focusing on specialized aspects of the inspection program, as requested.

Comments:

APPENDIX A-47
FOOD SAFETY AND INSPECTION SERVICE
SCIENCE AND TECHNOLOGY DIVISION

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Slaughter Plant Activities

Initiative: Develop quantitative risk assessment (QRA) methodology for application to decision making on pathogen reduction strategies

Activity: Quantitative assessments if applied to meat and poultry production practices can greatly assist in deciding on the public health risks of a system or change in system. The agency is attempting to develop principles from chemical hazard risk assessment models to microbiologic hazards, including infectious dose-response models.

Start Date: 10/92 **End Date:** ongoing **Method of Reporting Final Results:** Not applicable

Staff Years expended or required for completion: 6-8

Estimated Expenditures or Appropriations Required for Completion: \$150,000 (FY 1994 appropriation)

Evaluation Mechanisms in Place or Planned: Not applicable

Status: Proposed risk assessment projects identified. Completed on project on human health risk of chloroform in poultry meat from chlorine use in chill tanks.

Findings: Quantitative risk assessment has little history as applied to microbiological hazards. Significant effort will be required to develop appropriate models.

Future Action: Further contract work planned to develop microbial model methodology, infectious dose-response data, etc. Seeking advice of the Advisory Committee for Microbiologic Criteria in Foods as to application of QRA techniques.

Comments: There are no definitive end dates as this is ongoing research and development.

APPENDIX A-48
FOOD SAFETY AND INSPECTION SERVICE
PROGRAM REVIEW AND ASSESSMENT OFFICE

Meat and Poultry Inspection Modernization Program

TYPE OF ACTIVITY: Program Review and Internal Assessment

Initiative: Determine effectiveness of New Turkey Inspection System (NTIS)

Activity: Conduct reviews of the 26 plants operating under NTIS, including interviews with inspectors and supervisory personnel.

Start Date: October, 1993 **End Date:** November, 1993 **Method of Reporting Final Results:** Individual plant reports. Comprehensive report on findings.

Staff Years Expended or Required for Completion: 2.0

Estimated Expenditures (including dates) or Appropriation Required for Completion: Approximate Salary and Benefits Expended (October - January, 1993) = \$ 140,000. Approximate Travel Expenditures (October - November, 1993) = \$ 18,000

Evaluation Mechanisms in Place or Planned: Follow-up reviews will be scheduled.

Status: Comprehensive report under review within the Department; to be issued in final shortly. Short-term corrective actions were taken during reviews. Longer-term corrective actions in progress are being monitored by inspection workforce.

Findings: Of the 26 plants reviewed, 16 had effective process control, 6 needed stronger quality control, and 4 had serious control problems. Interviews indicated most supervisors and inspectors support NTIS.

Future Action: Specific recommendations in the report are under final review.

Comments:

APPENDIX 4.—ADDITIONAL STATEMENTS SUBMITTED FOR THE MAY
25, 1994, HEARING RECORD

REINVENTING THE FEDERAL FOOD SAFETY SYSTEM
LUTHER C. MCKINNEY
SENIOR VICE PRESIDENT FOR LAW AND CORPORATE AFFAIRS
THE QUAKER OATS COMPANY

TESTIMONY SUBMITTED TO THE
HUMAN RESOURCES AND INTERGOVERNMENTAL RELATIONS SUBCOMMITTEE
HOUSE GOVERNMENT OPERATIONS COMMITTEE
MAY 25, 1994

TOO MANY COOKS IN THE KITCHEN

The regulatory framework for food is complex. Thirty-five federal laws govern food safety and quality. Twelve federal agencies have varying food regulation responsibilities. With more than 15 percent of the GNP generated through farming and food processing, it is understandable why so many agencies want a piece of the food policy pie. What is not so understandable is why Congress has shared the bureaucratic wealth so broadly and in ways that are often contradictory.

In addition to facing differing requirements of food safety laws, food companies must also contend with infighting among the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration and other federal agencies. On top of federal regulatory overlap, reinvigorated federalism in the 1980s brought us still another complicating dimension — expanded state regulation. Most issues fought out at the state level are fought in several states — often simultaneously, often with differing outcomes, and always at great expense.

While the federal Food and Drug Administration (FDA) has done a more than adequate job of ensuring a safe food supply for those products it regulates (all processed food products), its effectiveness has been somewhat limited by dwindling resources and infighting among the various federal and state agencies with responsibility for food safety oversight. I do not believe that the FDA lacks the proper enforcement authority to ensure a safe food supply. Nor do I believe that additional government revenues—through increased taxes or the imposition of user fees—are necessary to bolster FDA's regulatory oversight. Rather, FDA's performance can be improved by focusing its oversight on real—rather than perceived—health risks; reallocating government resources to programs that clearly protect human health and away from outdated or unnecessary programs; improving government performance generally; consolidating conflicting laws and regulations; and by establishing a single food regulatory agency.

I would also add that the new food safety direction that the FDA is taking under HACCP (Hazard Analysis Critical Control Points) is promising. Rather than inspecting to ensure safety after a food product is manufactured, HACCP analyzes critical control points along the entire manufacturing process to ensure a safe product at the end of

manufacturing. FDA is to be commended for its work on HACCP for seafood and its stated plans to extend HACCP to other food areas. I would caution, however, that HACCP should be implemented first for food processes that pose the greatest risk to human health.

THE STATE OF REGULATION TODAY

In attempts to protect the public good through regulation, Congress, the Administration, and state agencies are sometimes successful. A number of laws on the books today are necessary, make sense, and have been implemented rationally. Even the good laws and regulations, however, compare unfavorably with the truly effective regulatory job done by consumers who use their purchasing power to tell manufacturers what they want and how they want it made.

Interest groups, industry and consumers have many times worked in tandem to improve the nation's regulatory environment. In cases where consumers have been allowed to direct the marketplace, they have effectively managed change. Unfortunately, consumer concerns have often suffered from being misdirected by interest groups which are active in the legislative process. The government is too often influenced by special interests who benefit with enhanced fundraising from creating or maintaining certain regulatory programs. The government also moves slowly in removing ill-conceived policies, often because of bureaucratic inertia. Even when government officials get it right and enact science-based laws to improve public health, inflexible wording renders these regulations obsolete as science evolves. The results have been painful: misallocated government resources, stifled innovation, and costly marketplace distortions.

Few issues have been debated so intensely, and with so much misinformation as the issue of food safety. Even with the safest, cheapest, and most abundant food supply in the world, the U.S. food industry is constantly striving to improve our safety record. Clearly, with nearly 10,000 Americans dying annually from food-related illnesses, there are improvements in food safety which must be made. Significant new technologies have been developed to assist in this effort. Yet these technologies are under attack. By playing to public fears of change and the unknown, interest groups have almost stopped the use of irradiation and biotechnology, technologies which can help improve food safety. And they continue to waste valuable government and industry resources in fighting to eliminate many valuable pesticides without scientific justification.

In addition to unnecessary costs created when regulations are based on fear or consumers are kept from valuable information, significant resource misallocations result when government regulations are simply out of date. These regulations also pose significant problems – inhibiting innovation, diverting scarce government resources, and adding consumer costs. The USDA's meat inspection and grading programs, the Delaney Clause, and a number of farm programs were all implemented with the best of intentions. But all have failed to keep pace with science or the marketplace.

Consumers have done a much better job than government in eliminating products from the marketplace that no longer meet their needs. While governments can be influenced by interest groups, marketing can only go so far in convincing a consumer to buy something that an individual neither needs nor wants. Consumers are even more effective in leading manufacturers to develop and distribute products they desire. A 1992 Grant Thornton Survey of American Manufacturers found customer demand as the key source of new product ideas according to 56 percent of manufacturing executives. By contrast, 20 percent of executives believe that government regulation is the single largest impediment to new products and no one mentioned the government as a source of new product ideas.

GOVERNMENT'S PROPER ROLE

In the food sector, government legitimately regulates in three critical areas: protecting human health, ensuring truthful commercial communication, and promoting marketplace consistency.

Given the potential health and safety risks related to food consumption as well as the opportunities to improve human health through diet, it is little wonder that the government has been extensively involved in developing a wide-ranging food regulatory framework. The key objective of food safety regulations and programs is to assure that food products will not adversely affect health because of unsanitary production conditions and practices, improper food handling and packaging, or harmful contaminants or food additives, such as drugs or certain pesticides. These regulations often include standards intended to ensure that the U.S. supply is both safe and wholesome. Carefully-crafted food and nutrition regulations and programs can also improve human health by, among other objectives: establishing science-based dietary guidelines; educating consumers on the link between diet and health; encouraging technological innovation to produce healthier low-cost foods; and fostering truthful consumer communication.

While there is little debate about the government's role in setting and enforcing minimum health and safety standards for the food supply, there is a great deal of debate in defining "minimum." Preventing meat contaminated with harmful bacteria from entering the marketplace clearly protects public health and enhances consumer confidence. But it is not so clear that as much as \$1 billion should be spent by the economy to reduce a theoretical cancer risk from 1 in 900,000 to zero.

Ensure Truthful Communication

Most interested parties also believe that the government should help ensure that consumers receive truthful and nondeceptive commercial information. The "Electricating Liniment" sold by Sears for 29 cents a bottle in the early part of this century may have had value to consumers, but it certainly was not, as the advertising claimed, a "certain cure for rheumatism, cuts, sprains, wounds, old sores, corns, galls,

bruises, growing pains, contracted muscles, lame back, stiff joints, frosted feet," etc. And "Dr. Barker's Blood Builder" was not a cure for everything from acne to ulcers to syphilis. The government rightly has a role in keeping such claims from being made. Moreover, implied deception can be as harmful as outright misinformation if it misleads consumers. Government plays an appropriate role in preventing any knowing deception through unstated implications of advertising or label claims.

Although ensuring truthfulness sounds simple, unfortunately it is not. Critics frequently say that the federal government moves too slowly to stop certain labeling and advertising practices that some consider false or misleading. However, the government must follow tough standards when restricting commercial speech protected by the First Amendment.

The new Nutrition Labeling and Education Act (NLEA) is a recent example of needed consumer communication regulation. This new law will help ensure the truthfulness of information set forth on food labels. For a company which prides itself on providing healthy foods to consumers, the standards set in the NLEA help its attempts to reach consumers with accurate information.

Promote Consistency

The third major area for federal regulation is in promoting marketplace consistency. Most manufacturers promote consistency by spending millions of dollars annually on quality controls which ensure that consumers are guaranteed of purchasing the same quality product no matter when or where they buy it. Not every manufacturer, however, has this long-term view, forcing the government to play a necessary role in ensuring marketplace consistency. The meat grading standards used by USDA, while judging the wrong quality measure, at least ensure that consumers are getting generally similar products, whether purchased in Kansas City or Chicago. Grade A large eggs are similar in Seattle or Sarasota. Under the new NLEA, food product labels will read the same no matter what state a product is produced or sold in, or whether it is a USDA- or FDA-regulated product.

IMPROVING REGULATIONS -- WHAT NEEDS TO BE DONE

While human health protection, truthful commercial communications and marketplace consistency are important areas of government regulatory activity, resisting the tendencies to over-regulate industries, micro-manage companies and leave outdated regulations intact are government's most difficult challenges. In order to meet these challenges, three key changes in how regulations are imposed will need to be made. First, priorities will need to be established on what to regulate. Next, market-oriented laws will need to be established based on those priorities. Finally, the bureaucracy which implements and oversees those market-oriented regulations will need to be streamlined.

Set Priorities

Clearly, the government should focus its resources where the greatest health problems lie. Federal government resources have dwindled significantly in the past decade, as entitlement programs and interest payments on the national debt have helped create extensive annual deficits. The need to cut back on spending means government must make difficult choices among programs and that remaining scarce financial resources be used efficiently. The most effective means to prioritize health and safety resources is to use science as the basis for sound decision-making and to conduct cost-benefit analyses to determine what regulatory options are most effective.

Use Science

Sound science should be used to determine which problems the government will tackle. Addressing problems based on agendas other than protecting public health leads to wasted resources and ineffective programs to address health and environmental concerns. Risk assessment science can allow regulators to determine which problems significantly affect health and safety. This science uses lifetime animal bioassays, human epidemiological studies and other data to determine whether a chemical or activity is a human health hazard. The skill of researchers in making these determinations is improving, and putting federal resources toward its improvement would be a worthwhile investment.

Battles over risk assessment science have been occurring for decades, but have become sharply focused in recent months as the EPA moves closer to enforcing the "zero-risk" Delaney Clause. A particularly strong battle exists over whether the use of the Maximum Tolerated Dose (MTD) in doing cancer risk assessments provides researchers with real information about a chemical's cancer risk. Regardless of the outcome of this debate, certainly our regulatory system is better off being based on good, but improving science, rather than on no science at all.

Furthermore, there is little doubt that the federal government should use one scientific standard. In one law alone, the Clean Air Act Amendments of 1990, Congress managed to use just about every conceivable risk level for varying portions of the law alternating between the "non-numerical" negligible risk standard and specific numerical requirements such as a one-in-one-million level. Food safety law is governed by the zero-risk Delaney Clause of the Federal Food, Drug and Cosmetic Act for processed foods and by a different section of the FFDCa for raw commodities, which says only that the residues on those commodities must be limited to a level which protects public health. These inconsistencies in regulations make compliance difficult and also call into question the legitimacy of such contradictory regulations.

Consider Cost/Benefits

Risk assessment is a terrific technological innovation, but its results need to be placed in perspective. The warning labels required under California's Proposition 65 voter

initiative have panicked parents who, when filling their childrens' sandboxes, read that the sand they are buying "may contain ... crystalline silica ... known to the State of California to cause cancer," even though that sand is typical beach sand.

The need to consider the costs and benefits of a regulation is perhaps clearest when considering the impact Proposition 65 would have had on milk had it not been for a case-specific exemption. As you know, Vitamin A has tremendous health benefits, and is a key ingredient in the federal government's push for improved nutrition. Vitamin A is also considered by the State of California to be a reproductive toxicant and as such under Proposition 65 would have, without a special exemption, meant that milk would be required to carry a health hazard warning. An environmental hazard warning would certainly have reduced milk consumption, and therefore, the overall health of children. The costs of hazard labels on milk clearly outweighed the benefits. Without providing agencies with the flexibility to weigh costs and benefits as part of every safety law, legislators run the risk of harming consumers. Regulations without this flexibility also run the strong risk of desensitizing consumers to real risks by needlessly warning them about every potential hazard.

In addition to using scientific measurements to determine the need for a particular regulation, comparative cost-benefit analysis must be done to ensure that the resources spent by companies and the government provide the most consumer benefit. Environmental interest groups have argued for many years that there is no cost too great to protect the environment. We all know that is not the case, particularly in the current era of dwindling resources.

Establish Market-Oriented Laws

Once government has decided what our nation's science-based regulatory goals should be, it faces another difficult challenge. It must establish such standards in manners which allow industries to reach goals as efficiently as possible. While any market-oriented law must be set nationally, regulators can choose to meet their goals through either behavior-based taxes, or standards which provide for flexible implementation. Industry benefits from market-based laws through improved cost-efficiency. Government benefits from both financial savings and easier oversight.

Flexible Implementation

The Clean Air Act is providing valuable lessons on the importance of establishing regulatory targets and providing industry with the flexibility to achieve those goals cost-effectively. The act sets a specific goal of removing 10 million tons of sulfur dioxide from the nation's atmosphere, but allows utilities with excess SO₂ emissions to purchase permits for exceeding the emissions standard from others who are able to clean up below their required level at less cost. The government goal is reached, but in a manner which is cost-efficient for industry and ultimately consumers.

As Congress moved the Clean Air Act through the legislative process, even some skeptical environmental groups began to realize they could convince Congress to set strict environmental standards if the law provided flexibility for companies and industries on how to meet those standards. The Environmental Defense Fund has been a leader among the environmental community in pushing for market-oriented regulations. Even the traditional "command and control" groups – those favoring laws which require companies to take specific actions by specific dates so that compliance is easily determined – are beginning to see the value of flexible market-oriented systems as the way for future regulations.

Behavior-Based Taxes

While tradable permit systems represent a dramatic step forward from command-and-control regulations of the past (at least I hope they are in the past), a number of economists argue that the purest market method for achieving behavioral control is through fees or taxes. It is clearly better to tax an activity you want to discourage than to tax activities you are attempting to stimulate. Pollution control efforts are often cited as prime candidates for testing this theory. Environmental taxes have become increasingly popular from the government's perspective in recent years as environmental goals are joined by government revenue needs.

Environmental taxes are certainly a more efficient way to attack environmental concerns than command-and-control regulations, but I am cautious in advocating them. Given the revenue needs of the federal government, they likely could be imposed simply to raise revenue and not to change behavior, with traditional "command-and-control" regulations continuing unabated. As a replacement for current taxes on investment, research and development, and other activities with long-term economic benefits, however, carefully-crafted environmental taxes might make sense. For a behavior-based tax to be effective in achieving its goal, it must meet several important criteria. First, the tax must be imposed at the appropriate level of responsibility. If the goal is to influence the composition of packaging materials, for example, it would be far more effective to target the packaging material manufacturer rather than the end-user. Second, the tax must be applied in a manner which allows the target to escape the tax by changing its behavior. Finally, and most importantly, the tax must be imposed on an activity that truly affects human health, and for which the costs and benefits are clearly understood.

Federal Uniformity

Federal uniformity is also a key element of making the marketplace work and allowing U.S. manufacturers to be globally competitive. Supporters of President Reagan made a key mistake in 1980 while arguing for a reduced regulatory role for the federal government. That mistake was to assume that the states would not pick up the regulatory slack, which indeed they did, in a manner which was both costly and inefficient for industries that manufacture or sell products on a national or international basis.

During the 1980s, many states assumed an increasing regulatory role in such diverse and nationally important areas as solid waste and packaging, food labeling and air quality. Industry has been forced to invest significant resources in attempting to prevent a patchwork quilt of conflicting, confusing and contradictory state regulation. Obviously, such state regulation poses extreme burdens on national manufacturers and distributors. Under this diversified regulatory framework, we find it as difficult to do business nationally as a baseball player would find it to play ball in a game with 50 umpires – many with different rule books. For example, in the solid waste arena, the grocery industry faces unworkable and often contradictory proposals in almost every state. The warning labels on food required under Proposition 65 in California are placing a tremendous burden on industry. The NLEA provided uniformity for most label claims, but unfortunately does not address the Prop-65 mandated warnings.

Improve Government's Performance

In the area of food safety, the government can take several steps to improve its efficiency. Some steps are fairly simple; others require a fundamental redesign of the food regulatory system.

Establish a Single Food Agency

An important step would eliminate duplication, confusion, and delay by placing all authority and responsibility for the safety of the nation's food supply in one agency. A GAO report prepared in June 1992 noted several problems caused by the current system:

"Although officials of all the agencies [responsible for food regulation] recognize the need for prompt referrals of food safety problems to the responsible agency for action, such referrals are frequently not made...Agencies have also acted to protect their own jurisdictions, thus reducing their flexibility to respond to changing consumption patterns and emerging food safety issues, such as the control of food poisoning outbreaks associated with salmonella."

While a single food agency would help eliminate many food safety problems faced in the United States, it will not be enough if, as the GAO notes, Congress does not also eliminate conflict which exists in food laws. "A new structure for food safety inspection and enforcement, based on uniform enforcement authorities and an assessment of the risk that food products pose to public health, could help the Congress oversee, fund and enact legislation on the federal food safety inspection system," the GAO stated. But by paring these laws and making one agency responsible for implementation, government will undoubtedly enhance its oversight and enforcement, and at a lower cost.

Government officials and agencies must also be held accountable through performance standards. Each day, Quaker's performance is measured by the stock market and

quarterly by its public earnings statements. If the company does not perform adequately, consequences follow: lower earnings, lower pay, demotions, and job loss. Few government agencies have implemented performance standards. Texas is a notable exception with its attempt to implement performance measures for its investment of taxes. In this era of constrained budgets, all states and the federal government must institute performance standards.

Government agencies must also have sufficient resources to do their jobs. For years, inadequate funds prevented the Food and Drug Administration from effectively addressing its numerous regulatory responsibilities. FDA receives only one-tenth of 1 percent of the federal budget for regulation of the food industry, an industry that produces more than 15 percent of the nation's gross national product.

Prescription drug manufacturers became so disenchanted with the FDA's slow process for approving new drugs that they agreed in 1992 to pay user fees for additional staff to review drug-approval applications. Speedier FDA review means that profitable new products reach the marketplace faster. In the food industry, enhanced government safety measures directly benefit consumers, and thus additional funds for FDA should appropriately come from general revenue sources.

But significant new revenue sources may not be needed to enhance the performance of food regulating agencies. FDA could receive increased funding if the government eliminated inefficient, obsolete, and unnecessary programs and reallocated its resources to essential efforts based on sound science.

May 23, 1994

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources and
Intergovernmental Relations
B-372 Rayburn Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

On behalf of the National Restaurant Association and the 730,000 foodservice establishments nationwide, I appreciate the opportunity to share with you our views on the federal food safety system.

The foodservice industry strongly supports a safe food delivery system. Such a system is necessary for ensuring people will dine out. However, it is important to remember that it is local jurisdictions which have the primary responsibility for ensuring safe food in restaurants through local health codes and standards. The federal system plays an ancillary role by providing model health code language and providing the inspection and regulatory oversight for most of the food items which are delivered to restaurants. However, it should be noted that this is an important role not only in providing safe food, but also in inspiring confidence in the food supply system.

You have asked us to assess the capability of the Food and Drug Administration (FDA) to ensure the safety of the nation's food supply. One must first realize that the food supply cannot be ensured. Aggressive regulatory action can only reduce risks. Thus, a more appropriate question becomes: How much are we willing to pay to reduce risks further? Alternatively, we might ask: How much risk are we willing to accept? In other words, are foodservice operators and/or consumers willing to pay more in money, regulatory intrusion, and altered food taste and texture, in order to achieve diminishing returns in terms of reduced risks?

Our answer to your query is that we believe the FDA is doing an adequate job, but does not currently have sufficient resources to meet all of their statutory responsibilities. While additional federal support would address this shortcoming, we also believe there must be a renewed focus of the agency's efforts and a review of the confusion caused by overlaps with other agencies, most notably USDA/FSIS and EPA. There are instances when such overlaps are merely amusing, such as when a pizza manufacturer must meet two separate federal requirements, one for meat products (USDA) and another for non-meat (FDA). Other times they are clumsy, such as when FDA must sample produce and test for pesticide residues but those allowable levels are set by EPA. Similarly, the FDA issues guidelines for the use of sanitizing chemicals in foodservice establishments,



Honorable Edolphus Towns

May 23, 1994

Page two

but EPA registers those chemicals and their use conditions, and the day-to-day monitoring of use is normally handled by state or local agencies. In perhaps the most frustrating illustration, under the latest FDA guidelines (Food Code 1993, a model ordinance) restaurant operators are required to cool shell eggs, milk, or shellfish to 41°F within four hours of receipt. Yet, because these commodities are covered by other laws and regulations in transit, they may have been held for days at temperatures of 50°F to 60°F. Certainly, if these products are volatile in the restaurant, they should be more so in transit, but FDA guidelines and regulations merely attack the most available site, rather than the more critical one.

Regarding the Hazard Analysis Critical Control Point (HACCP) system, the FDA has issued proposed rules for establishing a system of inspection for seafood importers, wholesalers, and processors. We generally regard this as a positive, if overdue, step because it tends to focus control efforts on those areas known to cause disease such as temperature abuse. The proposal also allows the flexibility to shift emphasis based upon differing risks in various products or locations. The proposal could result in an increased cost for seafood. However, that may be offset by increased quality, consistency, and consumer confidence. The largest problem with the proposal lies in the inability to monitor conditions at sea where the first, and often most critical, abuses may occur.

The design of FDA's inspection program has differing rates of efficacy based on the food products involved and the stage within the food processing, distribution, and preparation chain. For example, FDA's system of controls for low-acid canned foods are extremely effective, as evidenced by the rarity of incidents of *Clostridium botulinum*. FDA has been less effective in the area of imported foods. Overall, we would probably rate the existing FDA system as competent given the available resources and directions.

Our thoughts on an optimal federal food safety system are outlined below:

- 1) Single agency authority from the farm (or water) to the table. However, this should not pre-empt local administration at the retail/foodservice level.
- 2) Risk-based and flexible.
- 3) Preventive, as opposed to corrective.
- 4) Educational as to the realistic limits of the system and necessary downstream controls.

Honorable Edolphus Towns

May 23, 1994

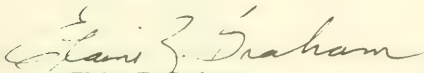
Page three

- 5) Sufficient resources including proper levels of knowledge and training for all professional and field personnel.
- 6) Sufficient statutory authority, including the repeal of anachronistic laws and regulations.

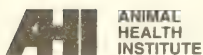
Regarding the proposed elimination of the FSIS, it is preferable from our point of view to have one government agency to have authority over food safety. In this context, we favor the elimination of FSIS and the transfer of their regulatory functions to FDA. However, this should not be interpreted to mean that FSIS has not been effective and, furthermore, it should not be assumed that such a transfer would result in more competent regulatory oversight. In our opinion, it would simply be preferable to consolidate oversight responsibilities in one agency.

We appreciate your willingness to consider our views on this important subject.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elaine Z. Graham".

Elaine Z. Graham
Senior Director, Government Affairs



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"Food Safety Programs at the Food and Drug Administration"

Testimony of the Animal Health Institute

before the

**Human Resources and
Intergovernmental Relations Subcommittee
of the House Government Operations Committee**

May 25, 1994

Chairman Towns and members of the committee, thank you for the opportunity to provide comments to you on this important topic. The Animal Health Institute (AHI) has reviewed recommendations put forth by the National Performance Review to consolidate responsibilities for all federal food safety functions into one agency -- the Food and Drug Administration, and applauds your commitment to the safety of the nation's food supply.

AHI represents manufacturers of animal health products -- the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep pets healthy. The animal health products industry strenuously ensures the safety of the products it manufactures. The safe use of these products are vital for maintaining animal health, and vital for producing safe food for consumers of meat, milk and eggs.

Bringing an animal health product to market is a complex process. Only one in 20,000 discovered chemicals ever makes it from the laboratory to the farm. And only one in 200 potential drugs makes it through pre-clinical testing and approval. All of this takes time. It can take three to four years to license a new animal vaccine, and a decade or more to take an animal drug from discovery to approval.

It is also expensive. In 1993, the animal health products industry spent nearly \$400 million on research and development. For a \$2.4 billion industry, that means that about 20 cents of every dollar earned by the industry is spent researching and developing new products; this ratio is substantially higher than similar industries.

The primary reason that the product development, review and approval processes are so time-consuming and costly is because of safety tests. All animal health products go through a stringent seven-step process that involves testing to discover a product, testing to approve the product, and testing to monitor the product once it's been approved.

Manufacturers and government work together on all of this testing -- testing for effectiveness, testing for safety, testing for quality and testing for residues -- protects the producer, the animal and the consumer. The public can be assured that when an animal health product is used according to label instructions, its manufacturer and the federal government have certified that it's effective and safe. And that is important.

Industry believes that its products, when used properly, are crucial to the safety of the U.S. food supply. AHI has developed several programs centered around the idea of proper product use and food safety. First, AHI has developed its Food Safety Network, which links all segments of animal agriculture to food retailers and consumer groups. The network relays facts about meat, milk and egg safety to people providing food safety information and offers opportunities to work together on crucial food safety issues.

AHI also worked with the numerous producer groups to develop quality assurance programs aimed at informing producers about proper handling and raising of farm animals. Specifically, AHI worked with the producer groups to develop proper drug use components stressing the importance of selecting the correct animal health products, using them properly and adhering to withdrawal times. AHI continues to work closely with these producer groups on their quality assurance programs to provide the most current information available on the proper use of animal health products. In fact, AHI recently published a comprehensive booklet describing the basic components of each groups quality assurance programs and distributed over 35,000 copies to producers nationwide. Plans are underway to distribute even more to help increase producer participation in these important programs.

AHI has also produced a number of other communication tools (videos, slide shows, etc.) to continuously underscore the importance of using animal health products properly.

Obviously, AHI member companies are committed to ensuring the safety of the products they manufacture, and hence a safe food supply. That is why AHI is so interested in the issue of developing a single food safety agency. And, while AHI does not have a formal position on this issue, it is concerned about the possible effects -- both positive and negative -- of moving all food safety programs into an agency that is already short on financial resources and long on mandates from Congress and the administration.

The Food and Drug Administration has the responsibility of reviewing and approving animal health product applications which are vitally important for the future success of the animal health products industry. Therefore, an effective FDA is vitally important to the future of the industry. The idea of altering any food safety jurisdictions must be thoroughly reviewed and discussed by all relevant parties -- government, consumer groups, agriculture, and industry -- in order to devise a food safety system that adequately addresses important concerns and does not over-burden any agency.

There are several items AHI believes must be addressed before any changes are implemented. First, a study of USDA and FDA strengths and weaknesses (pertaining to developing and monitoring food safety initiatives) needs to be conducted before merging food safety missions and programs. This helps better define food safety missions, identify areas for improvement, and target areas currently performed admirably.

Given AHI's relationship with the FDA and its Center for Veterinary Medicine (the industry's chief regulator), several current situations lead the industry to question whether FDA has adequate resources to take on another regulatory responsibility.

The first is the current animal health product availability situation. Over the last decade, AHI member companies have experienced a marked reduction in the number of products being approved by FDA's Center for Veterinary Medicine, despite a doubling of research and development expenditures. In addition, the average time from submission of an application to the time it is reviewed has increased substantially.

Statute requires that a new drug application be reviewed within 180 days -- it has been averaging 990 days. All of this suggests that FDA may be overworked and understaffed for completing its current missions.

Second, if responsibility for food safety is to be consolidated into one agency, specific missions, goals, and comprehensive performance standards need to be developed beforehand. The food safety function of the federal government is too important to the health of Americans to consider any changes without first setting clear goals and standards for performance. Again, all relevant parties need to be heard during the development process so that the strongest, most workable system can be established.

And third, a thorough examination of funding sources for an expanded FDA needs to take place to ensure that adequate funding is available. AHI believes that any proposed food safety agency needs to be fully funded by U.S. Treasury dollars and not by deficit reduction user fees. AHI has been actively following the current FDA appropriations process and is concerned that the agency may already be facing funding difficulties. To add an additional regulatory responsibility, especially one as costly as regulating and monitoring the safety of the food supply, would further burden FDA.

These and other considerations must be thoroughly discussed by your committee and other legislators. The Animal Health Institute appreciates the opportunity to submit this testimony to the Human Resources and Intergovernmental Relations Subcommittee. The industry remains committed to the safe production of meat, milk and eggs, and looks forward to working with Congress and regulators on continuing efforts to ensure that America's food remains safe.

APPENDIX 5.—ADDITIONAL MATERIAL FOR THE MAY 25, 1994,
HEARING RECORD



April 15, 1994 / Vol. 43 / No. 1 RR-5

MMWR

*Recommendations
and
Reports*

MORBIDITY AND MORTALITY WEEKLY REPORT

**Addressing Emerging Infectious
Disease Threats:
A Prevention Strategy for
the United States**

Executive Summary

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control

and Prevention (CDC)

Atlanta, Georgia 30333



Contents

Introduction.....	1
Background	3
The CDC Prevention Strategy.....	9
Implementation.....	12
References.....	16

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Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States *Executive Summary*

Ingenuity, knowledge, and organization alter but cannot cancel humanity's vulnerability to invasion by parasitic forms of life. Infectious disease which antedated the emergence of humankind will last as long as humanity itself, and will surely remain, as it has been hitherto, one of the fundamental parameters and determinants of human history.

— William H. McNeill in *Plagues and Peoples*, 1976

Summary

The spectrum of infectious disease is changing rapidly in conjunction with dramatic societal and environmental changes. Worldwide, explosive population growth with expanding poverty and urban migration is occurring; international travel and commerce are increasing; and technology is rapidly changing—all of which affect the risk of exposure to infectious agents.

Recent examples of important emerging infectious diseases include prolonged diarrheal illness due to waterborne *Cryptosporidium*, hemorrhagic colitis and renal failure from foodborne *Escherichia coli* O157:H7, pneumonia and middle-ear infections caused by drug-resistant pneumococci, and rodentborne hantavirus pulmonary syndrome. These diseases as well as resurgent diseases (e.g., tuberculosis and cholera) illustrate human vulnerability to microorganisms in the environment. Three recent reports by the Institute of Medicine document the need to address emerging infectious disease threats.

In partnership with representatives from health departments, other federal agencies, medical and public health professional associations, and international organizations, CDC has developed a strategic plan to address emerging infectious disease threats. The plan contains four goals that emphasize surveillance, applied research, prevention and control, and public health infrastructure. To ensure sustainability, plan implementation will be approached in stages, as a long-term endeavor with emphasis on extramural programs. As health-care reform proceeds, priority should be given to strengthening partnerships between health-care providers, microbiologists, and public health professionals to detect and control emerging infectious diseases.

INTRODUCTION

Once expected to be eliminated as a public health problem, infectious diseases remain the leading cause of death and disability-adjusted life years (DALYs) worldwide (1) and are among the leading causes of death in the United States (2). Dramatic changes in society, technology, and the environment, together with the diminished effectiveness of certain approaches to disease control, usher in an era wherein the spectrum of infectious diseases is expanding, and many infectious diseases once thought to be controlled are increasing (Box 1).

The term "emerging infectious diseases" refers to diseases of infectious origin whose incidence in humans has either increased within the past two decades or threatens to increase in the near future (3). To effectively address emerging infectious diseases, CDC has developed a strategic plan emphasizing surveillance, research, and prevention activities necessary to maintain a strong defense against infectious diseases that affect, or threaten to affect, the public's health.

The goals of this plan address priorities for surveillance, applied research, prevention and control, and public health infrastructure, respectively:

- Goal I.** Detect, promptly investigate, and monitor emerging pathogens, the diseases they cause, and the factors influencing their emergence.
- Goal II.** Integrate laboratory science and epidemiology to optimize public health practice.
- Goal III.** Enhance communication of public health information about emerging diseases and ensure prompt implementation of prevention strategies.
- Goal IV.** Strengthen local, state, and federal public health infrastructures to support surveillance and implement prevention and control programs.

BOX 1. Examples of emerging infectious diseases, 1993

Diseases in the United States

- Coccidioidomycosis
- Cryptosporidiosis
- Drug-resistant pneumococcal disease
- *Escherichia coli* O157:H7 disease
- Hantavirus pulmonary syndrome
- Influenza A/Beijing/32/92
- Vancomycin-resistant enterococcal infections

Diseases outside the United States

- Cholera, Latin America
- Dengue, Costa Rica
- Diphtheria, Russia
- *E. coli* O157:H7, South Africa and Swaziland
- Multidrug-resistant *Shigella dysenteriae*, Burundi
- Rift Valley fever, Egypt
- *Vibrio cholerae* O139, Asia
- Yellow fever, Kenya

BACKGROUND

The Concept of Emergence

Many factors or combinations of factors can contribute to disease emergence. Newly emergent infectious diseases may result from changes in or evolution of existing organisms; known diseases may spread to new geographic areas or human populations; or previously unrecognized infections may appear in persons living or working in areas undergoing ecologic changes (e.g., deforestation or reforestation) that increase human exposure to insects, animals, or environmental sources that may harbor new or unusual infectious agents (Table 1) (4–7).

Infectious diseases may reemerge because of either the development of antimicrobial resistance in existing agents (e.g., gonorrhea, malaria, pneumococci) or breakdowns in public health measures for previously controlled infections (e.g., cholera, tuberculosis, and pertussis) (3).

The Burden of Infectious Diseases

In the United States and elsewhere, infectious diseases increasingly threaten public health and contribute substantially to the escalating costs of health care. For example, childhood ear infections are the leading cause of patient visits to pediatricians, and the incidence of visits for these infections increased 150% during 1975–1990 (8). In addition, infectious agents may be causing diseases previously considered noninfectious: *Helicobacter pylori* has a well-established association with peptic ulcer disease and gastritis (9); sexually transmitted human papillomavirus is associated with cervical cancer (10); and infection with hepatitis C virus—now recognized as a leading cause of chronic liver disease and cirrhosis in the United States—occurs in an estimated 150,000 persons annually (11). *Chlamydia* infections have long been implicated in infertility and, more recently, have been tentatively associated with coronary artery

TABLE 1. Factors contributing to emergence of infectious diseases*

Categories	Specific examples
Societal events	Economic impoverishment; war or civil conflict; population growth and migration; urban decay
Health care	New medical devices; organ or tissue transplantation; drugs causing immunosuppression; widespread use of antibiotics
Food production	Globalization of food supplies; changes in food processing, packaging, and preparation
Human behavior	Sexual behavior; drug use; travel; diet; outdoor recreation; use of day care facilities
Environmental changes	Deforestation/reforestation; changes in water ecosystems; flood/drought; famine; global warming
Public health infrastructure	Curtailment or reduction of prevention programs; inadequate communicable disease surveillance; lack of trained personnel (e.g., epidemiologists, laboratory scientists, and vector and rodent control specialists)
Microbial adaptation and change	Changes in virulence and toxin production; development of drug resistance; microbes as cofactors in chronic diseases

*Adapted from reference 3.

disease (12), and rodentborne hantaviruses may play a role in hypertensive renal disease (13).

Infectious diseases account for 25% of all visits to physicians each year, and antimicrobial agents are the second most frequently prescribed class of drugs in the United States. (14,15). Direct and indirect costs of infectious diseases (e.g., economic losses and days of disability) may exceed an estimated \$120 billion. Such approximations, however, most likely underestimate the burden of infectious diseases. For example, the *International Classification of Diseases* (ICD-9) distributes infectious diseases across several categories, obscuring their public health impact (e.g., the classification of endocarditis among cardiovascular diseases and the classification of meningitis and middle-ear infections among diseases of the nervous system and sense organs, respectively).

The Threat of Emerging Infections

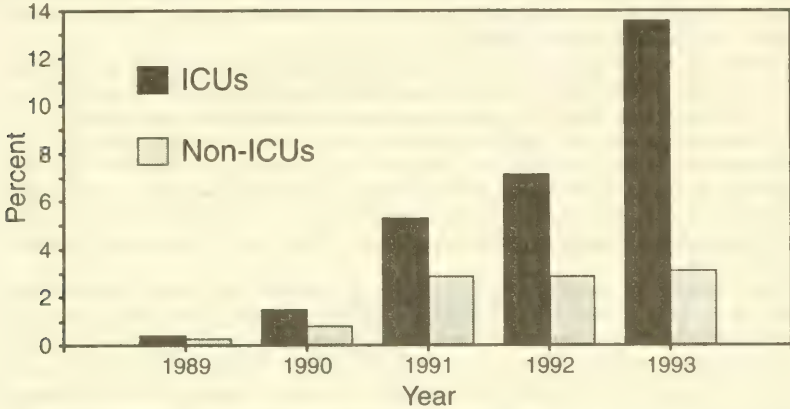
As a consequence of changes in society, technology, and the environment, pathogens evolve or spread, and the spectrum of infectious diseases expands. Emerging infections, such as human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), illustrate that no nation can be complacent regarding human vulnerability to microorganisms in the environment. Since the early 1970s, the U.S. public health system has been challenged by other newly identified pathogens and syndromes, such as Legionnaires' disease, Lyme disease, toxic shock syndrome, hepatitis C virus, and, most recently, hantavirus pulmonary syndrome (16-23). Moreover, the incidence of many diseases widely presumed to be under control—such as cholera (24), dengue (25), yellow fever (26), and tuberculosis (TB) (27,28)—has increased in many areas or spread to new regions or populations throughout the world. Because of widespread use and misuse of antimicrobial drugs, their effectiveness in treating common bacterial infections is diminishing, resulting in prolonged illnesses, higher mortality rates, and higher health-care costs (Figure 1) (29-35).

Emerging infections are particularly serious in persons with lowered immunity, such as those infected with HIV and those receiving immunosuppressive therapy for cancer or organ transplantation—populations whose numbers are increasing (Figure 2). Other groups that may be disproportionately affected by emerging infections include the elderly; persons being cared for in institutional settings, such as hospitals and nursing homes; and persons with inadequate access to health care, such as the homeless, migrant farm workers, and others of low socioeconomic status.

The number of children attending day care facilities has increased in the past decade as more mothers of young children have entered the work force. These children, now numbering more than 11 million, are at a substantially increased risk for enteric infections, such as hepatitis A, giardiasis, and cryptosporidiosis; acute respiratory illnesses; and middle-ear infections. Also, children who become infected can infect other members of a household (36).

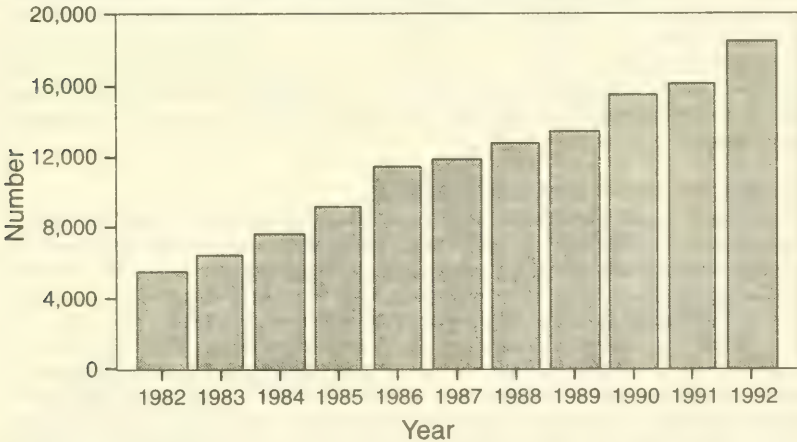
Emerging infections transmitted by contaminated public water supplies place entire communities at risk. In the spring of 1993, contamination of a municipal water supply with the intestinal parasite *Cryptosporidium* caused the largest recognized outbreak of waterborne illness in the history of the United States; an estimated 403,000 persons in Milwaukee, Wisconsin, had prolonged diarrhea, and approximately 4,400 persons required hospitalization (personal communication, Jeffrey P. Davis, commu-

FIGURE 1. Percentage of nosocomial enterococci reported as resistant to vancomycin isolated from infections in patients in intensive-care units (ICUs) and non-ICUs, by year — National Nosocomial Infections Surveillance system, 1989–March 31, 1993*



*Treatment options for patients with nosocomial infections associated with vancomycin-resistant enterococci are limited, often to unproven combinations of antimicrobials or experimental compounds.

FIGURE 2. Number of organ transplants — United States, 1982–1992



Source: United Network for Organ Sharing, Scientific Registry Data, July 23, 1993.

nicable disease epidemiologist, Wisconsin). Large segments of populations may also be exposed to emerging infections through contaminated food products. For example, in 1993, hamburgers contaminated with the bacterial pathogen *Escherichia coli* O157:H7 and served at a fast-food restaurant chain caused a multistate outbreak of hemorrhagic colitis (bloody diarrhea) and serious kidney disease, resulting in the deaths of at least four children (37,38).

Limitations in both surveillance and the availability of appropriate diagnostic tests constrain public health efforts to prevent and control outbreaks. Both *E. coli* O157:H7 and *Cryptosporidium* were first recognized as important human pathogens in the early 1980s, but neither has received adequate public health attention (Figure 3).

Exposure to certain animals also poses a risk for emerging infectious diseases. Hantavirus pulmonary syndrome, first recognized in the southwestern United States in 1993, has been linked to exposure to infected rodents in more than a dozen states. More than 60 cases have been detected; of those, more than half have died (Figure 4) (20-23).

Once considered "exotic," tropical infectious diseases are having an increasing effect on the U.S. public. Recent examples include severe illness and at least one death due to cholera among international airline passengers arriving in California (39); malaria among residents of southern California and immigrants in North Carolina (40,41); fever and heart failure in New York and Canada among patients who received blood transfusions contaminated with the bloodborne parasite (*Trypanosoma cruzi*) that causes Chagas' disease in Latin America (42,43); and a newly described form of leishmaniasis among troops returning from the Persian Gulf conflict (44,45).

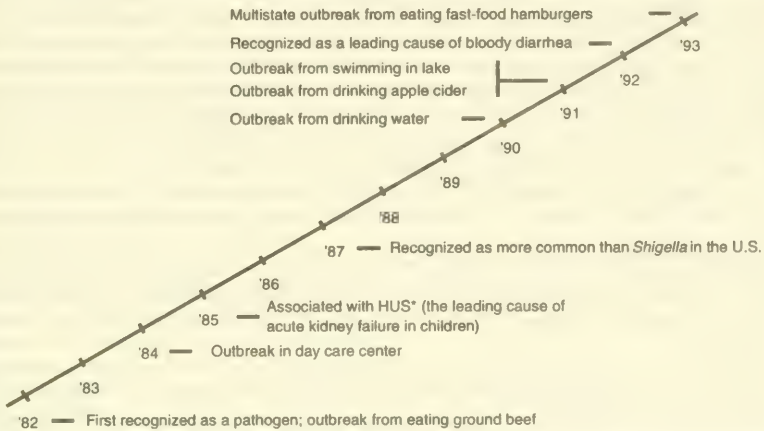
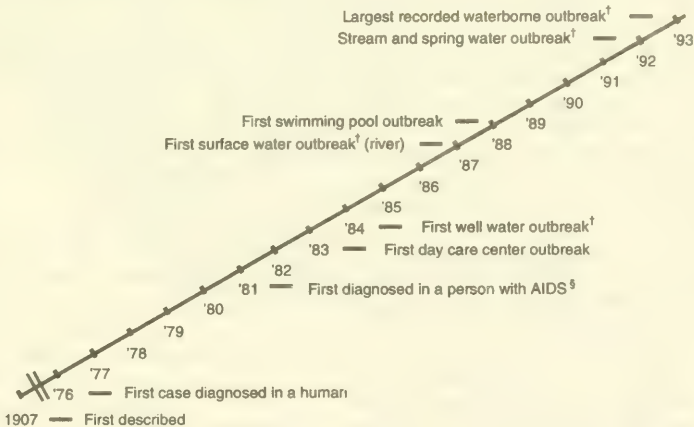
From a historical perspective, cholera, smallpox, and plague are examples of infectious diseases that spread globally with devastating impact, often during periods of rapid economic change or population growth (7). Today, travel and commerce have fostered the worldwide spread of pathogens such as HIV/AIDS and influenza, as well as the reemergence of cholera as a global health threat—consistent with a perspective that "the microbe that felled one child in a distant continent yesterday can reach yours today and seed a global pandemic tomorrow" (46). These examples underscore the fact that emerging infections can affect persons in geographically widespread areas, regardless of factors such as lifestyle, cultural or ethnic background, or socioeconomic status.

Preparing to Confront Emerging Infections

The public health infrastructure is insufficiently prepared to confront today's emerging disease problems. Domestic surveillance systems for most infectious diseases are inadequate and global surveillance is fragmentary at best. For example, foodborne and waterborne disease outbreaks may be either unrecognized or detected late, and the magnitude of the problem of antimicrobial drug resistance is unknown.

Surveillance of infectious diseases in the United States depends on voluntary collaboration between CDC and state and local health departments, which depend on reporting by health-care professionals of a limited number of specific, recognized infectious diseases. Reporting is generally incomplete. Results of a recent survey conducted by the Council of State and Territorial Epidemiologists underscore the inadequacy of existing infectious disease surveillance by documenting the limited number of professional positions dedicated to infectious disease surveillance in most

FIGURE 3. Emergence of foodborne and waterborne pathogens — United States

Escherichia coli O157:H7 (1982-1993)*Cryptosporidium* (1976-1993)

* Hemolytic uremic syndrome.

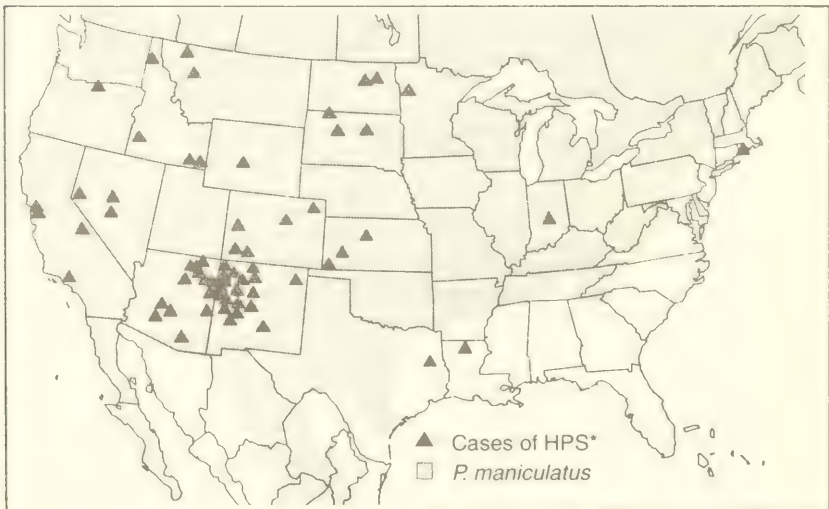
[†] Involved municipal water supplies.[§] Acquired immunodeficiency syndrome.

states. For example, in 12 of the 50 states surveyed, no "professional position is dedicated to surveillance of foodborne and waterborne diseases. Funding for infectious disease surveillance is restricted primarily to diseases for which public health crises have already developed. In 1992, more than 95% of federal funds allocated to states for infectious disease surveillance were targeted to four disease categories (i.e., TB, HIV/AIDS, sexually transmitted diseases [STDs], and selected vaccine-preventable diseases) (personal communication, M. Osterholm, Council of State and Territorial Epidemiologists survey on surveillance). However, no federal resources are provided to state and local health departments to support the national notifiable disease system. In addition, the ability of state public health laboratories to support the surveillance and control of infectious diseases has diminished (47).

Timely recognition of emerging infections requires early warning systems to detect such problems so they may be promptly investigated and controlled before they evolve into public health crises. Prompt detection of these new threats depends on careful monitoring by effective surveillance systems; on a thorough understanding of trends in incidence and distribution of known infectious agents; and on effective communication among clinicians, clinical laboratory personnel, and public health professionals.

The ability to detect what is new or reemerging depends on the capacity to identify and track both the routine and the unusual. Like radar or "early warning" systems that detect threats to national security, surveillance with appropriate laboratory support is a critical element in the effective defense against these diseases. Surveillance systems

FIGURE 4. Distribution of *Peromyscus maniculatus* and number of recognized cases of hantavirus pulmonary syndrome, selected geographic regions, as of March 23, 1994



*Hantavirus pulmonary syndrome.

are the most important tools for determining which infectious diseases are emerging or receding.

Effective surveillance also provides a basis for evaluating the outcome of both public health and personal medical-care programs. Surveillance information is essential to ensure the use of the most efficacious and cost-effective approaches to preventive, as well as curative, health care. Regardless of the direction of health-care reform, surveillance will be critical to the meaningful evaluation of new prevention programs.

In addition to comprehensive and innovative surveillance systems, effective preparation for detecting, preventing, and controlling emerging infectious diseases requires sound foundations in professional expertise, laboratory support, and research capability to strengthen the infrastructure needed to address the ongoing, but often changing, threats from emerging infections. Despite the continued emergence of such threats, support for applied research and control efforts has declined over the past decade.

Three recent reports by expert committees convened by the National Academy of Science's Institute of Medicine (IOM) have indicated that the ability of the U.S. public health system and health professionals to address emerging infectious disease problems is in jeopardy (3,48,49). The earliest of these reports, "The U.S. Capacity to Address Tropical Infectious Disease Problems" (48), documented the inadequate state of readiness to recognize, treat, or control infectious disease threats emanating from the tropics—regions that have yielded microbial threats such as Lassa fever and Ebola viruses, chloroquine-resistant malaria, and penicillin-resistant gonorrhea. The second report, "The Future of Public Health," concluded that the U.S. public health system is in disarray. This report emphasized that the U.S. approach to public health has too often been crisis driven, an approach that is costly because it constrains the institution of cost-saving preventive strategies (49).

The third IOM report, "Emerging Infections, Microbial Threats to Health in the United States," emphasized the ongoing threat to domestic and global health from emerging infectious diseases (3). The report provided specific recommendations for CDC, the National Institutes of Health, the Food and Drug Administration, the Department of Defense, and other federal and state agencies for addressing microbial threats to health in the United States and elsewhere. This report emphasized a critical leadership role for CDC in a national and global effort to detect and control emerging infectious disease threats.

THE CDC PREVENTION STRATEGY

To effectively detect and prevent emerging infections, improvements are needed in public health systems, program design, and infrastructure. To accomplish these improvements and to achieve the objectives of *Healthy People 2000*, CDC has developed a strategy to address these microbial threats. Because meeting the broad challenge of emerging infections requires interaction, cooperation, and coordination among a wide range of public and private organizations, the development of this strategy has taken place in partnership with state and local health departments, other federal agencies, academic institutions, health-care providers, medical laboratory personnel, and international organizations.

The prevention strategy outlined in this document contains four critical goals that address, in a broader context, specific IOM recommendations for revitalizing the ability to identify, contain, and, most importantly, prevent illness from emerging infectious diseases (Box 2).

Goal I (Surveillance) emphasizes the improvement and expansion of surveillance capabilities for infectious diseases in the United States and internationally. This goal includes plans for strengthening local and state public health programs for infectious disease surveillance, establishing provider-based sentinel surveillance networks, and creating population-based Emerging Infections Epidemiology and Prevention Centers at different sites throughout the United States (Table 2). Also included are plans for a global consortium of closely linked epidemiology/biomedical research centers to promote the detection, monitoring, and investigation of emerging infections (Box 3). Other objectives emphasize improved detection and monitoring of trends in antimicrobial resistance in both institutional and community settings; expansion of field investigations and epidemic response capabilities; prevention of foodborne and waterborne infectious diseases and improved knowledge of the distribution of animal reservoirs and vectors associated with human infectious diseases.

Goal II (Applied Research) focuses on applied research and the integration of laboratory science and epidemiology with public health practice. Emphasis is placed on determining how behavioral factors influence exposure to new infections; better characterizing the health burden of both well-established and emerging infections; and evaluating the effectiveness and economic benefit of strategies to prevent emerging infectious diseases. An additional focus is the development and application of improved laboratory techniques for the identification of new pathogens and the expanded use of molecular epidemiologic techniques in investigating emerging diseases. Supporting the national Childhood Immunization Initiative by conducting vaccine efficacy studies and improving rapid response capabilities for vaccine development and delivery is also a priority. A final focus is the reestablishment of CDC extramural programs to promote effective partnerships with public agencies, universities, and private industry and to support applied research in surveillance, epidemiology, and prevention of emerging infections.

Goal III (Prevention and Control) addresses enhanced communication of public health information and the implementation of prevention strategies for emerging infections. Highlighted under this goal are proposals for expanded dissemination of the *MMWR*, as well as other important public health information sources. Another priority is the creation of an accessible and comprehensive infectious disease database for the United States that increases awareness of infectious diseases and promotes public health action. The database will contain current information on topics such as antimicrobial resistance, foodborne and waterborne disease outbreaks, travelers' health, antimicrobial drug availability, vaccine-preventable diseases, and vaccine guidelines. This goal also addresses the development and implementation of guidelines for preventing emerging infectious diseases and the provision of critical prevention materials.

BOX 2. Summary of goals and objectives for preventing illness from emerging infectious diseases**Goal I: Surveillance**

Detect, promptly investigate, and monitor emerging pathogens, the diseases they cause, and the factors influencing their emergence.

Objectives:

- Expand and coordinate surveillance systems for the early detection, tracking, and evaluation of emerging infections in the United States.
- Develop more effective international surveillance networks for the anticipation, recognition, control, and prevention of emerging infectious diseases.
- Improve surveillance and rapid laboratory identification to ensure early detection of antimicrobial resistance.
- Strengthen and integrate programs to monitor and prevent emerging infections associated with food/water, new technology, and environmental sources.
- Strengthen and integrate programs to monitor, control, and prevent emerging vector-borne and zoonotic diseases.

Goal II: Applied Research

Integrate laboratory science and epidemiology to optimize public health practice.

Objectives:

- Expand epidemiologic and prevention effectiveness research.
- Improve laboratory and epidemiologic techniques for the rapid identification of new pathogens and syndromes.
- Ensure timely development, appropriate use, and availability of diagnostic tests and reagents.
- Augment rapid response capabilities for vaccine production and delivery and expand evaluation of vaccine efficacy and the cost effectiveness of vaccination programs.

Goal III: Prevention and Control

Enhance communication of public health information about emerging diseases and ensure prompt implementation of prevention strategies.

Objectives:

- Use diverse communication methods for wider and more effective delivery of critical public health messages.
- Establish the mechanisms and partnerships needed to ensure the rapid and effective development and implementation of prevention measures.

Goal IV: Infrastructure

Strengthen local, state, and federal public health infrastructures to support surveillance and implement prevention and control programs.

Objectives:

- Ensure the ready availability of the professional expertise and support personnel needed to better understand, monitor, and control emerging infections.
- Make available state-of-the-art physical resources (e.g., laboratory space, training facilities, and equipment) needed to safely and effectively support the preceding goals and objectives.

Goal IV (Infrastructure) deals with issues relating to local, state, and federal infrastructure, particularly personnel and physical resources. Points of emphasis include maintaining expertise in rare or unusual infectious diseases and establishing training programs that emphasize the diagnosis of infectious diseases. A public health laboratory fellowship in infectious diseases is proposed. Also emphasized is the need for state-of-the-art physical resources such as laboratory space, training facilities, and equipment. Laboratory capabilities must be maintained in a manner that optimizes flexibility and "surge capacity" so that unanticipated public health threats can be adequately, efficiently, and safely addressed. Plans for expanding facilities for maintaining specimen banks of etiologic agents and clinical specimens are also a priority.

IMPLEMENTATION

This plan reflects CDC's commitment to meet the urgent public health challenge of important emerging infectious diseases. The need to proceed rapidly is made more urgent for many reasons. Many diseases pose an immediate danger. For example, methicillin-resistant *Staphylococcus aureus*, a common cause of hospital infections, may potentially develop resistance to vancomycin (29,50); penicillin resistance is spreading in *Streptococcus pneumoniae* (29,31,51); the potential exists for extension of the current cholera epidemic in Latin America to the Caribbean Islands (24); and *Vibrio cholerae* O139, a new strain for which existing cholera vaccines are ineffective and prior infection with *V. cholerae* O1 affords no protection, is spreading throughout

TABLE 2. Potential projects for Emerging Infections Epidemiology and Prevention Centers, United States

Potential center locations	Center Projects					
	Unexplained deaths of possible infectious etiology in young adults	Foodborne disease surveillance and prevention	Prevention of opportunistic infections in HIV-* infected inner-city populations	Drug resistance in nursing homes and day care facilities	Febrile and diarrheal illness in migrant farm workers	Etiologic agents of community-acquired pneumonia
Northeast	X	X	X			
Mid-Atlantic	X	X	X	X		X
Southeast	X	X	X		X	
South	X	X	X		X	X
Midwest	X	X		X	X	
Southwest	X	X		X		X
West	X	X	X	X	X	
Northwest	X	X		X	X	X
U.S. Pacific Islands	X	X				X
U.S. Caribbean Islands	X	X	X			

*Human immunodeficiency virus.

southern Asia (Figure 5) (52,53). Changing food-industry practices, dietary choices, and globalization of food supplies will bring new challenges to provide a diet safe from pathogens such as *Salmonella sp.* and *E. coli* O157:H7 (37,38,54-57). Ongoing investigations of hantavirus pulmonary syndrome document that the geographic distribution of this infection goes beyond the desert Southwest (23). These infectious disease problems emphasize the necessity of expeditiously implementing this plan through a balanced intramural and extramural effort.

The implementation of the goals and objectives in this plan is relevant to health-care reform. Examples of relevant issues include prolonged hospitalizations caused by hospital-acquired infections; increased morbidity and treatment costs resulting from antimicrobial drug resistance; and excessive burdens placed on public and private health-care delivery facilities because of community-wide outbreaks of food-borne and waterborne infections.

Some of the activities listed in this document are already in the planning stages and will be implemented soon. Many of the proposed activities need further development

BOX 3. Examples of potential members of a global consortium of epidemiology/ biomedical research programs/ centers

Existing networks

- CDC Field Epidemiology Training Programs
- International Clinical Epidemiology Network
- International Office of Epizootics Worldwide Information System
- Pan American Health Organization-CDC Dengue Surveillance Laboratory Network
- Pan American Health Organization Polio Eradication Laboratory Surveillance Network
- World Health Organization Arbovirus and Hemorrhagic Fever Collaborating Centers
- World Health Organization Global Influenza Surveillance Network

Existing research facilities

- Caribbean Epidemiology Centre, Trinidad
- CDC: National Center for Infectious Diseases Field Stations (Côte d'Ivoire, Guatemala, Puerto Rico, Kenya, Sierra Leone, and Thailand)
- Department of Defense: U.S. Army Research Facilities (Brazil, Kenya, Thailand) and U.S. Naval Research Facilities (Egypt, Indonesia, Peru, Philippines)
- Food and Agriculture Organization Reference Centers (Argentina, Brazil, Colombia, Czech Republic, France, Germany, Hungary, Kenya, Panama, Senegal, Spain, Sri Lanka, Thailand, United Kingdom, Uruguay, and the United States)
- French Scientific Research Institute (e.g., Senegal, Congo, Côte d'Ivoire)
- Instituto de Nutrición para Centroamérica y Panamá, Guatemala
- International Center for Diarrhoeal Disease Research, Bangladesh
- National Institutes of Health, National Institute of Allergy and Infectious Diseases-supported facilities (Brazil, Colombia, Israel, Mali, Mexico, Philippines, Sudan, Uganda, Venezuela, and Zimbabwe)
- Pasteur Institutes (e.g., Algeria, Central African Republic, French Guiana, Iran, Madagascar, Morocco, New Caledonia, Senegal, and Vietnam)

in full cooperation with other federal agencies, state and local health authorities, academic institutions, professional societies, private industry, and others. With this document serving as both a guide and a first step, implementation will be based on public health priorities and resource availability. This process will be approached in stages, as a long-term endeavor with sustainable impact and emphasis on extramural programs (Box 4).

The strategy of this plan is based on repeated experience demonstrating that it is less costly to anticipate and prevent infectious disease threats than to react with expensive treatment or containment measures to public health crises. Public health policy and practice that combine investments in surveillance, laboratory research and training, and epidemiologic investigations with prevention and control efforts will reduce the impact of emerging infectious disease threats, in terms of both human suffering and economic losses.

BOX 4. Implementation: high priorities for 1994-1996

Goal I: Surveillance

- Strengthen notifiable disease surveillance at state and local levels.
- Establish two physician-based Sentinel Surveillance Networks to detect and monitor emerging diseases, such as unexplained adult respiratory distress syndrome, drug-resistant pneumococcal disease, and childhood illnesses characterized by fever and rash.
- Establish four population-based Emerging Infections Epidemiology and Prevention Centers to conduct focused epidemiology/prevention projects emphasizing foodborne and waterborne infectious diseases and potentially vaccine-preventable diseases.
- Strengthen and link four existing research facilities/networks for a global consortium to promote the detection, monitoring, and investigation of infections emerging internationally that could affect the health of U.S. residents.

Goal II: Applied Research

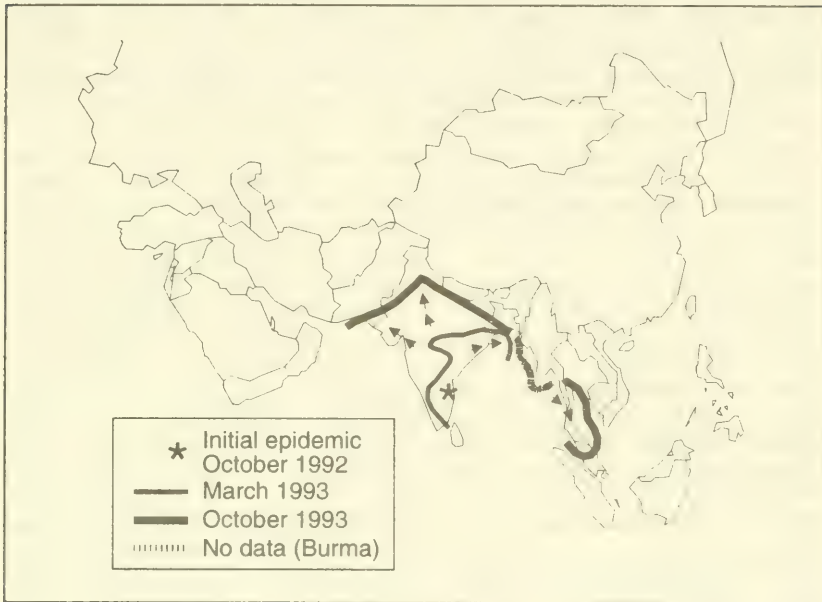
- Reestablish an extramural program to support emerging infectious disease prevention and control activities, such as evaluating the role of prescribing practices in the development of antimicrobial drug-resistant pathogens.
- Initiate prevention effectiveness studies to assess the impact of food preparation guidelines on the incidence of foodborne infections such as *E. coli* O157:H7 and *Salmonella enteritidis*.

Goal III: Prevention and Control

- Develop additional means to deliver laboratory and public health information informing health professionals about emerging infections and antimicrobial drug resistance.
- Develop and implement guidelines for the prevention of opportunistic infections in immunosuppressed persons.

Goal IV: Infrastructure

- Provide state-of-the-art training in diagnostic evaluation and testing for medical laboratory personnel to ensure the diagnosis and surveillance of emerging infections.
- Establish a public health laboratory fellowship in infectious diseases that will train medical microbiologists in public health approaches to diagnosis and molecular epidemiology.

FIGURE 5. Migratory path of *Vibrio cholerae* O139 (Bengal) — Asia, 1992–1993

Acknowledgments

Development of this plan began in December 1992 with consultation from the Board of Scientific Counselors of CDC's National Center for Infectious Diseases. Further guidance was provided at a meeting of infectious disease and public health experts in Atlanta in March 1993 and at a meeting of state and territorial public health epidemiologists, laboratory directors, and veterinarians in Minneapolis in June 1993. Drafts of this plan have also been reviewed by leaders of numerous medical, scientific, and public health organizations.

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CRS Report for Congress

FDA's Enforcement Authorities for Foods: Are They Adequate?

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SUMMARY

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides the Food and Drug Administration (FDA) with jurisdiction to regulate consumer products that account for nearly 25 cents of every dollar Americans spend. FDA is responsible for protecting the public health against unsafe products and through regulations promotes fair competition in the industries it regulates.

This report looks at FDA's statutory authorities and the tools FDA uses to implement its regulatory policies for foods. It then lists a series of potential administrative enforcement powers which FDA has identified which it believes would enhance its ability to ensure a safer food supply.

FDA is authorized to inspect food establishments (warehouses, processing plants) to determine whether a food complies with the standards established by statute and regulation. If a significant violation is found FDA can request that the Justice Department initiate an injunction, seizure, or criminal prosecution. FDA has authority to impose criminal sanctions on offenders whether or not these offenders had knowledge or intent to cause the violations, and to seize all violative products without the need for a court hearing. Yet FDA does not have some of the administrative enforcement tools that other Federal agencies are authorized to use. For example, FDA lacks authority to require that food-processing records be produced for inspection.

FDA has identified additional statutory authorities it believes would help ensure safe food handling and preparation. Some of these authorities would extend authorities FDA now has for medical devices or drugs to be used on foods; others would be entirely new enforcement tools. These include administrative records inspection; registration of food processors; presumption of interstate commerce; administrative civil monetary penalties; administrative temporary detention authority; administrative recall authority; administrative subpoena authority; authority to charge user fees for some food safety efforts; and enhanced authority to refuse entry on imported food where specific safety assurances from the foreign source are not met.

The food industry on the other hand argues that such administrative powers would be too broad, unnecessary, and could too easily be misused and abused. It thinks that FDA's span of authority is already extensive and does not believe that the food supply would be made safer by giving FDA greater enforcement authority.

TABLE OF CONTENTS

INTRODUCTION	1
FDA'S CURRENT ENFORCEMENT AUTHORITIES	2
TABLE 1. Selected FDA Statutory Enforcement Authorities ^a	3
STATUTORY AUTHORITY AND STANDARDS FOR FOOD SAFETY	5
FDA'S ADMINISTRATIVE ENFORCEMENT TOOLS	6
Inspections	7
Warning Letters	8
Recalls	8
Court Enforcement	9
TABLE 2. FDA Regulatory Activities for Foods and Cosmetics, Fiscal Years 1989-1993	12
Role of State and Local Governments	14
TABLE 3. FDA's Inspections of Domestic Food Establishments, Fiscal Years 1980-1993	15
PAST PROPOSALS FOR CHANGE	16
PROPOSALS TO INCREASE FDA ADMINISTRATIVE ENFORCEMENT AUTHORITY FOR FOODS	17
TABLE 4. FDA's Proposals For Expanded Administrative Enforcement "Tools"	18
APPENDIX A. Federal Agencies Comparable Enforcement Authorities and Dates When Basic Authority was Granted.	22
APPENDIX B. General FDA Enforcement Activities, Fiscal Years 1988-1993.	23
APPENDIX C. 1990 Statement of Enforcement Policy United States Food and Drug Administration	24

FDA'S ENFORCEMENT AUTHORITIES FOR FOODS: ARE THEY ADEQUATE?

INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (FFDCA) provides the Food and Drug Administration (FDA) with jurisdiction to regulate consumer products that account for nearly 25 cents of every dollar Americans spend. FDA is responsible for protecting the public health against unsafe products and through regulations promotes fair competition in the industries it regulates.

FDA's enforcement authority gets its "teeth" from the threat of strict penalties if a firm allows any adulterated or misbranded product, including foods, to enter interstate commerce.¹ FDA regulations for foods establish reasonable standards for quality, safety, and labeling. FDA's purpose is to provide guidance to the food industry, yet exercise enforcement authority as necessary.

Some in Congress and in the Administration have questioned whether the system by which FDA ensures food safety is adequate; whether it is as efficient and modern as necessary; and whether it suits the changing landscape of food production, processing, and distribution in this country. One aspect of this debate is centered on whether FDA needs further administrative enforcement tools to seek out violators, or whether existing court enforcement authorities are sufficient if rigorously exercised. In addition to considering added authorities for FDA, Congress is currently debating several proposals which would establish a single new food safety agency. Proposals for this new agency indicate that it would likely need greater enforcement tools than the statutes currently authorize.² FDA officials and some Members of Congress have in the past

¹The food industry vigorously opposes increasing FDA's enforcement tools, for it believes that the agency's current enforcement authority is sufficient. Moreover, industry officials claim that FDA has as strong court enforcement powers as any other Federal agency. FDA can seize all violative products merely by an "ex parte" court application, enjoin all violative activity, and obtain criminal sanctions against individuals and companies without proof of knowledge or intent.

²If Vice President Gore's National Performance Review recommendations are implemented FDA may be the recipient of meat and poultry product inspection responsibilities from the U.S. Department of Agriculture (USDA), and may inherit the enforcement authorities contained in the Federal Meat Inspection Act and the Poultry Products Inspection Act. See CRS Report No. 93-955 SPR, Selected Recommendations for Changes in the Federal Organization of Food Safety Responsibilities, 1949-1993. November 2, 1993. In addition, see two bills H.R. 3751 (Torricelli) and S. 1349 (Durenberger) which would each establish independent foods safety agencies, and S. 1750 (Metzenbaum), which would move all food safety responsibilities to the Consumer Product Safety Commission. Over the past few decades, numerous proposals have been advanced for reorganization of Federal food regulatory authorities, but none has been implemented.

suggested that several different types of intermediate administrative enforcement authorities would allow FDA to do a better job of protecting the health of U.S. consumers.

This report looks at FDA's statutory authorities and the tools FDA uses to implement its regulatory policies for foods. It then lists a series of potential administrative enforcement powers which FDA has identified which would enhance its ability to ensure a safer food supply.

FDA'S CURRENT ENFORCEMENT AUTHORITIES

The FFDCA and other statutes have vested responsibility in the Secretary of Health and Human Services to prohibit the entry into interstate commerce of adulterated or misbranded foods, drugs, devices, or cosmetics. The Assistant Secretary for Health has delegated these functions to the Commissioner of Food and Drugs. FDA officers or employees are therefore designated to take a variety of enforcement actions depending on the product.

Table 1 shows the authorities FDA now has and to which products they may apply. FDA inspectors, armed with these enforcement tools, inspect food companies to determine whether a food complies with FDA statutory mandates. If a significant violation is found FDA can request that the Justice Department initiate an injunction, seizure, or prosecution. Table 1 also shows some of the enforcement authorities that FDA currently has for other products such as medical devices or drugs that it does not have for foods.

Moreover, FDA does not have some of the administrative enforcement tools that other Federal regulatory agencies are authorized to use. For example, although FDA can now request food processing records (and food companies often willingly show their records), FDA lacks authority to require that these records be shown. FDA officials have proposed acquiring these additional authorities. The table in appendix A shows which Federal agencies have comparable enforcement authorities and the dates when each basic authority was granted.

TABLE 1. Selected FDA Statutory Enforcement Authorities*

FDA Statutory Authorities	Foods	Drugs	Devices	Cosmetics
Inspection Authorities for:				
Container Manufacturers	No	No	No	No
Commercial Testing Laboratories	No	Limited ^b	Limited ^b	No
Records Inspection	Limited ^c	Limited ^d	Yes	No
Subpoena Authority	No	Limited ^e	Limited ^f	No
Establishment Registration	Limited ^g	Yes	Yes	No
Presumption of Interstate Commerce	No	No	Yes	No
Recall Authorities:				
Administrative Recalls	Limited ^h	No	Limited ⁱ	No
Recall Reporting to FDA	Limited ^h	No	Limited ⁱ	No
Temporary Detention/Embargo Authority (domestic)	No	No	Yes	No
Civil Money Penalties:				
Administrative Civil Money Penalties	No	Limited ^{j,k}	Limited ⁱ	No
Court Ordered Civil Penalties	No	Limited ^l	No	No
Court Ordered:				
Seizure	Yes	Yes	Yes	Yes
Injunction	Yes	Yes	Yes	Yes
(continued)				

TABLE 1. Selected FDA Statutory Enforcement Authorities^a

FDA Statutory Authorities	Foods	Drugs	Devices	Cosmetics
Prosecution (misdemeanor and felony)	Yes	Yes	Yes	Yes

^aThe FDA also has jurisdiction over biological products (blood) and radiation-emitting products. This list of statutory authorities does not include all statutes for the listed articles.

^b"Limited" authority is explicit for prescription drugs and restricted devices; whether FDA has this authority for other products is open to interpretation.

^cThis authority is limited to infant formula.

^dFDCA specifies which records can be inspected relative to prescription drugs, and authorizes inspection of records that are submitted under new reporting requirements.

^eSubpoena authority is allowed in a hearing on drugs or in investigations that are relevant to abbreviated new drug application violations added under the Generic Drug Enforcement Act of 1992 (GDEA).

^fSubpoena authority is permitted in a civil money penalty investigation which is carried out relevant to a violation of medical device regulations.

^gThis registration is limited to persons introducing new infant formula into interstate commerce.

^hInfant formula recalls.

ⁱThis recall is used when the Secretary of Health and Human Services finds reasonable probability that the device would cause serious human adverse health consequences or death.

^jThis is permitted in the GDEA for abbreviated new drug application violations.

^kFor violations of the Prescription Drug Marketing Act (PDMA), as amended, the statute does not explicitly describe FDA's or the court's role in assessing civil money penalties, but FDA interprets the PDMA as authorizing these, subject to judicial review.

^lSome restrictions are imposed on violations of device regulations subject to civil money penalties.

Source: Food and Drug Administration. Office of Enforcement. Prepared by Joan Davenport, May 12, 1994. (301) 443-7400.

STATUTORY AUTHORITY AND STANDARDS FOR FOOD SAFETY

The basic standards for foods (including food additives) are established in sections 401, 402, 403, 404, 406, 408, and 409 of the FFDCA. Section 401 gives the definition and standards for food; Section 402 prohibits adulteration. A food is adulterated if it contains any poisonous or deleterious substance that may render it injurious to health.³ Section 403 prohibits misbranding, for example, if a food's label or labeling is false or misleading. Section 404 authorizes FDA to require licenses for any type of food that may be injurious to health by reason of contamination with microorganisms. Section 406 allows tolerances to be set for added poisonous ingredients in food. Section 408 provides for setting tolerances for pesticide chemicals on raw agricultural products.⁴ Section 409 provides for the pre-market approval of food additives and requires that they be shown to be safe.

Adulterated or misbranded food and those responsible for it are subject to the court enforcement actions provided by the Act including civil seizure actions, injunctions, and criminal prosecutions. FDA also enforces its food regulatory policies under a number of other statutes.⁵ These broad statutory directives have held up repeatedly in court and have become a guide for the practices of competing food firms.⁶

Title 21 of the *Code of Federal Regulations* (CFR), parts 100 to 199, as well as chapters 2,3,4,7, and 8 of the FFDCA, FDA's Compliance Policy Guides, and the 1993 Model Food Code provide guidance to food companies on the kinds of factors FDA inspectors look for. By setting standards, FDA indicates what constitutes an adulteration violation, or at what level of added poisonous or

³The FFDCA defines food in section 201. FDA interprets "food" as substances ingested primarily because of their aroma, taste, and nutritional value. FDA also examines the intended use of a substance in judging whether a substance is a food and decides whether the food is adulterated or misbranded. Foods are monitored to identify processing conditions that may cause products to be unsafe or to identify products which may present health hazards. Under the FFDCA certain foods must receive pre-market approval before entering interstate commerce: food additives, infant formula, and some health claims carried on food labels. Regulations promulgated under section 404, require companies that produce low-acid canned foods to register with FDA before they can begin marketing their products, and must comply with detailed good-manufacturing-practice regulations in order to stay in business. Otherwise, foods currently do not need any further clearance prior to being sold in retail stores.

⁴Under the Reorganization Plan No. 3 of 1970, the Environmental Protection Agency has responsibility for setting such tolerances and FDA has responsibility for enforcing such tolerances.

⁵The following laws also authorize FDA enforcement actions on foods: Fair Packaging and Labeling Act [15 U.S.C. 1451-1461]; Federal Anti-Tampering Act [18 U.S.C. 1365]; Tea Importation Act of 1897 [21 U.S.C. 41-50]; Federal Import Milk Act [21 U.S.C. 141-149].

⁶Pfeiffer, Eugene M. Enforcement Seventy-fifth Anniversary Commemorative Volume of Food and Drug Law. Food and Drug Law Institute Series. Edited and Published by the Food Drug Law Institute. 1984. p. 86

deleterious substances FDA would consider a product adulterated.⁷ FDA also publishes low-acid canned-food regulations and other standards for microbiological contamination, labeling, the umbrella good manufacturing practice (GMP) regulations⁸, and the quality control requirements for infant formula. The Environmental Protection Agency (EPA) establishes pesticide residue tolerances for each pesticide/food combination and FDA enforces these tolerances.

FDA'S ADMINISTRATIVE ENFORCEMENT TOOLS

FDA has a variety of tools that it uses to implement the FFDCA. For example, warning letters and other regulatory correspondence; detention; recalls; adverse publicity; certain product seizures; injunctions; import detention; "import alert" lists; misdemeanor prosecutions; and felony prosecutions are all used to ensure that FDA regulated industries including the food industry are complying with the applicable legal standards, as well as the guidance and regulations established by FDA (see appendix B).

For foods, formal court enforcement actions are just a part of the overall government/private industry relationship that an industry has with a regulatory agency.⁹ Although formal enforcement authority through the courts may be sought, FDA's power to require food companies to comply with the law comes largely from the threat of the use of this formal authority. (See appendix C for FDA's 1990 Statement of Enforcement Policy.)

⁷FDA monitors the marketplace by inspecting food establishments and import docks, collecting and analyzing food samples, and conducting investigations into the quality of products, both foreign and domestic. Inspectors identify many potential hazards, which can be corrected in time to prevent or minimize public exposure. Firms must correct problems identified by FDA inspectors, or run the risk of a possible enforcement action. Compliance activities include determining whether the problem has been corrected, whether the violative product has been removed from the marketplace, and whether legal action should be taken. Except when a violation is determined to be intentional or flagrant, or constitutes a danger to health, the management of a firm is generally given a second chance before FDA decides to pursue a legal action. Warning letters and voluntary recalls generally are used unless a court proceeding is the only way to enforce the FFDCA.

⁸Umbrella GMPs represent general standards of food processing and handling deemed necessary to avoid contamination of food with poisonous or deleterious substances, filth, or potentially harmful microorganisms. The regulation addresses layout and maintenance of facilities, personnel qualifications, equipment and utensils, processes and controls, and other measures required to ensure basic sanitation and cleanliness. Although these GMP regulations are not legally binding, violations of the general principles set forth in the regulation would allow FDA to prove a violation of section 402(a)(4) of the FFDCA. Taylor, Michael R. *Food Safety Regulation Food and Drug Law*. Edited and Published by Richard M. Cooper for the Food and Drug Law Institute. Washington, D.C. 1991.

⁹Hardy, Stuart B. *Assuring a Healthy Food Supply: A Case for Fundamental Reform of Regulatory Programs*. *American Review of Public Administration* v. 20, no. 4. Dec. 1990. p. 227-243.

CRS-7

The threat of sanctions works to get compliance when food companies, concerned about their reputations and brand name recognition, ensure their product's integrity. Another incentive for compliance of food companies is the risk of product liability exposure.

Inspections

FDA's inspection process is its most important enforcement tool under the FFDCA. FDA officials are authorized to enter and inspect, at reasonable times, any factory, warehouse, or establishment in which foods, (also drugs, devices, cosmetics, or certain electronic products) are manufactured, processed, packed, or held for the introduction into interstate commerce or to enter any vehicle being used to transport or hold such food, (drugs, devices, or cosmetics) in interstate commerce. Prior to entry and inspection, the FDA official must present credentials and a written notice to the owner, operator, or agent in charge. Inspections must take place at reasonable times, and within reasonable limits, and in a reasonable manner. Inspections can cover factories, warehouses, consulting laboratories, or vehicles and all pertinent equipment, finished or unfinished materials, containers, and labeling.¹⁰ The failure of a company to permit an inspection is a criminal offense.

Prior to leaving the premises, the FDA official making the inspection:

"shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that a food, drug, device or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."¹¹

If a sample of material is taken, the inspecting FDA officials must give a receipt to the owner, operator, or agent in charge. FDA officials can request access to, copy, and verify records only for restricted medical devices and prescription drugs, not for foods.¹²

¹⁰Section 704(a) of the FFDCA [21 U.S.C. 374(a)] authorized inspection "at reasonable times and within reasonable limits and in a reasonable manner." Section 301(f) states that refusal to permit entry into or inspection of a regulated establishment is prohibited.

¹¹FFDCA 21 U.S.C. 704 (b)

¹²Special provisions are set forth for drugs and devices: No inspection authorized (by the preceding sentence or for infant formula establishments)...shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection...[under other regulations.] [21 U.S.C. 704(a)(1)]

Formal action through judicial enforcement of the FFDCA has at times been protracted. The case study discussed in the text box, on the next page, shows how long it took FDA to move through the judicial system to bring about corrective actions in a new ethnic food processing establishment that had repeated sanitation problems.¹³

Warning Letters

If and when violations are found, FDA headquarters or District offices give the company's management the inspector's findings of alleged violations and discuss the findings with them. The current Commissioner of Food and Drugs, David A. Kessler, MD instituted a "warning letter system" on May 23, 1991. (Prior to this new policy, FDA sent two types of letters: notices of adverse findings and regulatory letters.) In the warning letter, FDA notifies the regulated food or other manufacturing factory or establishment of significant violations. The firm is asked to respond within 15 working days stating each step that has been or will be taken to completely correct the violations, and to prevent the recurrence of similar violations. If drugs or devices are involved, the warning letter places a hold on pending product or export approvals; if foods are involved, no temporary detention or embargo is authorized under the statute. To stop the sale of the food products, FDA must ask State authorities to detain the product. Publicity given to a warning letter within the trade creates pressure to comply with FDA's position.

Recalls

To FDA, a "voluntary correction or recall" is defined by regulations to mean the correction or withdrawal of a product that otherwise would be in violation of the FFDCA or other statutes administered by the agency. FDA has authority to require the recall of infant formula, but only limited recall authority for medical devices, biologics and electronic products. It lacks general "required" recall authority for foods and other FDA regulated products. (See table 1). FDA may begin formal judicial proceedings but the implicit or explicit threat of such formal action brings about most voluntary recalls. Under the voluntary recall process, FDA informs the company involved that other enforcement actions may be taken if a recall is not commenced in a timely fashion. FDA can also request an involuntary recall for food through an injunction.

¹³The food industry claims that there are no statutory or administrative reasons for such delay, other than lack of resources. A spokesperson for the industry claims that greater administrative efficiency and priority-setting would eliminate delay. FDA has shown progress in this area since this case occurred, according to food industry sources. FDA claims that it could have acted faster if it had additional records authorities and/or civil money penalties, which would have increased the pressure on the firm to correct the violations in a more timely manner.

CRS-9

First-time Inspection of a Food Manufacturer Results in Injunction

An initial inspection of Wai Man Realty Corporation, doing business as Daily Food Products, Incorporated, a manufacturer of Chinese ethnic foods (including various kinds of rice cakes, dried noodles, and soy bean drinks), was conducted by the New York District from July 16 through August 14, 1991. The gross conditions found at this company resulted in a recommendation for injunction on August 24, 1991.

The FDA district had become aware of the existence of the company through a consumer complaint about the company's product labels. The inspection revealed a virtual lack of sanitation in the manufacturing facility. All five floors of the building showed evidence of active infestation with insects and rodents on the floors, walls and food production equipment and machinery, as well as in the raw materials. In addition, numerous poor employee practices were found; employees handled egg contents with bare hands and washed their hands and faces in the same water that had been used for washing food.

FDA headquarters approved pursuing the case, but required an updated inspection. The updated inspection, conducted in October 1991, revealed essentially the same conditions. FDA then forwarded the case to the Department of Justice in November 1991 and subsequently forwarded it to the U.S. Attorney, Southern District of New York. Another walk through of the plant was conducted on January 30, 1992, and once again, filthy conditions were observed. A complaint and an order to show cause in connection with a motion for a preliminary injunction were filed on February 10, 1992 by the Dept. of Justice. Attorneys for the company came forward and, prior to a hearing before the judge, agreed to a consent decree requiring a total shutdown of the manufacturing plant on February 13. The consent decree provided for, among other things, a thorough cleanup, structural improvements in the building, and education in proper sanitation for the employees.

A March 1992 inspection of the plant found conditions to be satisfactory and the firm was permitted to resume operations.

Source: U.S. Department of Health and Human Services. Public Health Service. Food and Drug Administration. Office of Regulatory Affairs. Office of Enforcement. The Enforcement Story. The articles provide an update on FDA enforcement activities for the period October 1, 1991 through September 31, 1992.

Court Enforcement

The FFDCA authorizes the Justice Department to file a criminal suit on behalf of FDA in Federal court if a "person" (e.g., individual or corporation) commits any FFDCA prohibited act. The offense is a misdemeanor unless it is committed with intent to defraud or mislead or as a second offense after a prior conviction under the Act, in which case it is a felony. Before FDA refers an FFDCA criminal case to the Justice Department, FDA generally first gives notice and an opportunity to present views by those FDA contemplates prosecuting.¹⁴ A criminal prosecution can result in a fine and/or imprisonment. According to

¹⁴21 U.S.C. 335.

CRS-10

the food industry, this is the strongest criminal sanction possible because FDA need not prove knowledge or intent of the person or company violating the law.

Similarly, the Act authorizes the Justice Department to file an injunction action, on behalf of FDA, to halt violations of the Act. If a company under a court-imposed injunction violates a provision of the order, FDA can request a criminal or civil contempt of court action, or both.

Under the Act, FDA has civil monetary penalty authority which is limited to drugs and devices. (See Table 1.) Some monetary penalty authorities can be exercised by FDA; others only by a Federal court.

The Act provides for seizure and condemnation of articles that violate its provisions. Here, too, the action must be brought in a Federal court. The court may permit any party to a condemnation proceeding to obtain a representative sample of the article seized and a copy of FDA's analysis, prior to a trial contesting the seizure. Seizures cover all products in a store or plant. Prior to a court decision, the food products of a store or plant remain embargoed so effectively the company cannot conduct business while the issue is being resolved.

Any food, drug, device, or cosmetic condemned under this section ((d)(1)), shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds if sold, less the legal costs and charges, shall be paid into the U.S. Treasury. No article shall be sold under a decree contrary to this Statute or laws of the jurisdiction in which it is sold.¹⁵

The court may also direct that the article be delivered to the owner, be destroyed, or be brought into compliance with the provisions of the Act under the supervision of FDA. The expenses of the supervision while the products are in storage must be paid by the person obtaining release of the article under bond. The Act authorizes a seizure of a device that violates the Act regardless of any showing of a connection with interstate commerce. There is also no required interstate commerce connection in seizure actions brought against counterfeit drugs or oleomargarine or any adulterated or misbranded article manufactured within a territory. For the large majority of seizure actions brought by FDA, the government must establish that the violative article has a tie to interstate commerce, e.g., "when introduced into interstate commerce," or "after shipment in interstate commerce," or "held for sale after interstate commerce." FDA has successfully taken the position in court that a product satisfies the interstate commerce requirement if any component has crossed State lines. Only local agricultural produce is likely to be exempt from FDA jurisdiction.

FDA's jurisdiction over foods is limited to those in domestic interstate commerce and those offered for import into the United States. FDA collects and

¹⁵21 U.S.C. 334.

analyzes samples of those foods and conducts wharf examinations of foods offered for import.¹⁶ Table 2 lists all of FDA's formal regulatory actions for food and cosmetics over six years from fiscal year (FY) 1988 through 1993. FDA inspects far more domestic food manufacturing and processing establishments, but collects more import samples than domestic samples. Inspectors generally sample products to test whether the product complies with the law. Very few injunctions or criminal charges are levied each year; most enforcement actions taken by FDA are issuance of warning letters and the urging of voluntary recalls by food manufacturers.

¹⁶Wharf examinations and sample collections and analyses involve about nine percent of the over 1,100,000 lots of food imported annually into the United States. U.S. Dept. of Health and Human Services. Public Health Service. Food and Drug Admin. Justification of Estimates for Appropriations Committees. FY 1995. v. XII. p. 38.

**TABLE 2. FDA Regulatory Activities for Foods and Cosmetics*,
Fiscal Years 1989-1993**

	1988	1989	1990	1991	1992	1993
Establishment Inspections ^a (Adverse findings)	8,297 (3,075)	7,668 (2,927)	7,077 (3,044)	9,165 (3,490)	7,001 (2,828)	6,786 (2,766)
Domestic Samples Analyzed ^b (Adverse findings)	17,037 (2,446)	16,983 (2,216)	18,603 (2,163)	18,346 (2,508)	18,434 (2,558)	17,482 (2,248)
Import Wharf Examinations ^c	42,646	67,753	43,929	48,354	60,822	52,979
Import Samples Analyzed ^d (Adverse findings)	32,801 (11,648)	37,936 (14,294)	37,678 (15,080)	38,147 (13,487)	45,503 (21,926)	36,453 (16,900)
Warning Letters ^e	36	13	24	122	360	291
Recalls	470	570	725	566	569	663
Seizures	121	88	78	66	86	47
Injunctions	6	6	4	5	9	7
Criminal Prosecutions	13	5	5	2	12	2

*The data do not contain separate actions on cosmetics. Foods and cosmetics are lumped together. However, according to the FDA's Office of Enforcement which supplied the data, actions against food establishments and products make up more than 90 percent of these actions.

^a The number of different inspections made in food or cosmetic establishments to determine if they are in compliance with FDA enforcement statutes. Adverse findings means the number of inspections which were classified as either "official or voluntary action indicated."

^b The number of samples of products of domestic origin (or of foreign origin if collected in domestic channels of trade) analyzed to determine compliance with FDA enforcement statutes. Adverse findings means the number of

CRS-13

analyzed samples which failed to meet established standards and policy guides, or would for other reasons support a regulatory action.

c) The number of examinations made of products in import channels of trade that are sufficient in scope to determine whether the products are in compliance with FDA enforced statutes. By definition, all products accepted for import are in compliance.

d) The number of examinations made of products of foreign origin in import channels of trade analyzed to determine whether the products are in compliance with FDA enforcement statutes. Adverse findings means the number of analyzed samples which failed to meet established standards and policy guides, or would for other reasons support a regulatory action.

e) Until May 23, 1991, these numbers reflect only "regulatory letters" sent to companies after they had already received a "notice of adverse findings" letter describing the violations of the FFDCA. The numbers increase substantially after May 23, 1991, because FDA changed its policy and began issuing only one "warning letter" rather than two different letters: "notice of adverse findings" and "regulatory letters." Dr. Kessler decided that there was no need to alert companies who should comply with regulations without the first "notice of adverse findings" letter.

Source: Office of Planning and Evaluation. Planning and Management Communications Staff. Program Information and Analysis Group. U.S. Dept. of Health and Human Services, Public Health Service. Food and Drug Admin. FDA Quarterly Activities Report. Fiscal Years 1989, 1990, 1991, 1992, 1993.

Role of State and Local Governments

FDA also works closely with States and local governments by sharing many food safety enforcement responsibilities.¹⁷ State programs are typically lodged in health and/or agriculture programs. There is no requirement that States follow Federal standards unless the State officials are under contract with the FDA. There are more than 400 different State organizations and offices involved in these efforts. State and local officials may use standards adopted at the State level. Over many years, Federal and State officials have cooperated on food safety programs and States have followed FDA standards.

In January 1994, FDA published a Model Food Code as a reference for States so they would have available baseline standards when conducting inspections and testing samples from food establishments.¹⁸ The Model Code standards can be used and adopted by States if they so wish. About 45 States have enacted food provisions based on the FFDCa, other Federal statutes, and the Model Food Code. States use these standards as a guide to when enforcement actions would be necessary.

Most States have developed their own system of consumer protection through inspections of food firms at retail levels. For example, States and/or local governments conduct health and sanitation inspections in restaurants, cafeterias, congregate feeding programs, and food stores.¹⁹ This part of the safety net for foods involves the inspection and surveillance of over 500,000 restaurants or institutional food service outlets, 30,000 supermarkets, 200,000 grocery stores, and 1,500,000 vending sites.²⁰ Table 3 shows how FDA, with the assistance of State officials under contract with the FDA, carries out its surveillance and monitoring responsibilities. Inspection numbers have declined as resources were limited by constrained budgets and FDA inspectors concentrated on higher risk foods such as seafood, on imports, and on other products, such as blood.

¹⁷Foulke, Judith E. A Menu of Modern Safety Standards. FDA Consumer. Apr. 1994. p. 7-9. In addition, see U.S. Dept. of Health and Human Services. Public Health Service. Health People 2000. National Health Promotion and Disease Prevention Objectives. Full Report With Commentary. p.343-344.

¹⁸In 1913, the first serious effort was made to enlist the active cooperation of States in enforcing the FFDCa. State and Federal officials meeting in Washington, D.C., formed a committee to establish standards that would serve as a uniform guide for enforcement throughout the country. Today this guide is called the Uniform State Food, Drug and Cosmetic Act, and the most recent version was adopted by the Association of Food and Drug Officials, 1984.

¹⁹All 50 States have dairy inspection programs based on the Pasteurized Milk Ordinance jointly developed by the States, and all participate in the National Conference on Interstate Milk Shipments (NCIMS), which further assures nationwide regulatory uniformity. FDA serves as one member of this conference. FDA and States have also established an Interstate Shellfish Sanitation Conference along the same lines as NCIMS.

²⁰U.S. Dept. of Health and Human Services. Public Health Service. Food and Drug Admin. Justification of Estimates for Appropriations Committees. Fiscal Year 1995. v. XII. p. 38.

TABLE 3. FDA's Inspections of Domestic Food Establishments, Fiscal Years 1980-1993

FISCAL YEARS	NUMBER OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	NUMBER OF STATE-FDA CONTRACTED INSPECTIONS OF DOMESTIC FOOD ESTABLISHMENTS
1980	16,243	16,274
1981	20,528	16,697
1982	18,143	13,745
1983	16,441	11,419
1984	14,447	12,583
1985	12,463	11,933
1986	10,980	9,791
1987	9,656	6,929
1988	8,216	7,469
1989	7,565	7,776
1990	7,054	7,255
1991	9,195	7,956
1992	6,861	7,794
1993	6,607	7,354

Source: Public Health Service. Food and Drug Admin. Office of Regulatory Affairs. Prepared by John Lechus. (301) 443-2155.

FDA also contracts with or commissions State officials to conduct additional inspections such as inspections of low-acid canned-food establishments. There are also voluntary cooperative work-sharing programs, formalized with agreements between State and local officials and FDA. FDA officials admit that the system does not always work smoothly.²¹ In years past, Federal and State officials were criticized for "tripping over each other." FDA officials are working currently with State officials to be able to accept State laboratory and other data on quality assurance programs, so that FDA inspectors can concentrate more of their resources on large interstate enterprises and import inspections.

²¹Telephone conversation with Mr. Heinz Wilms, Director of the Division of Federal State Relations. Office of Regulatory Operations. Office of Regulatory Affairs. Food and Drug Administration. (301) 443-3360. March 9, 1994.

CRS-16

FDA receives information on potential hazards and violations from State and local groups as well as trade and professional associations, and consumer groups.²² Competitors are a primary source of complaints to FDA with information which often lead to some type of investigation.

PAST PROPOSALS FOR CHANGE

If Congress were to augment FDA's enforcement authorities, consideration would likely be given to administrative mechanisms that are either tools to persuade violating companies to comply with the Act or further sanctions. These mechanisms have become known as "intermediate enforcement tools." Some of these "tools," such as records inspection and civil money penalties, have been proposed and debated both in past Congresses and in recent discussion memos among the executive branch agencies.²³ Two bills introduced into the 102nd Congress during the first session contained additional "intermediate authorities": (1) H.R. 3642 introduced by Representative Waxman for himself and Mr. Dingell on October 24, 1991²⁴; and (2) S. 2135 introduced by Senator Edward Kennedy on November 27, 1991²⁵. These bills would have amended various sections of FFDCA, to extend enforcement authority coverage to include all FDA-related articles, such as medical devices and drugs. In addition, they would have granted additional tools to FDA to use in the agency's regulation of foods.²⁶ Neither proposal has been reintroduced during the 103d Congress.

²²Also early in the century, the Office of State Cooperative Food and Drug Control was established to exchange information, prevent duplication of efforts and encourage the participating State and local governments to assist one another. Federal and State officials had collaborated with each other on an individual-case basis to examine such problems as shellfish contamination in State waters.

²³David A. Kessler. Memorandum to the Secretary. Department of Health and Human Services. Subject: Food Safety Initiative--ACTION. March 12, 1993.

²⁴In the 102d Congress, H.R. 3642, The Food, Drug, Cosmetic, and Device Enforcement Amendments of 1991 had an original version, H.R. 2597, that had been introduced on June 7, 1991. Hearings were held on H.R. 2597, on July 19, 1991, by the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce. The Bush Administration and representatives of the food, drug, and device industries opposed this legislation. The Bush Administration refused to allow Dr. Kessler to testify on specifics of H.R. 2597. The Subcommittee on Health and the Environment marked up the bill on October 10, 1991, and a new bill was introduced, H.R. 3642. This latest version of the bill was reported out of the Committee on Energy and Commerce, but no further action was taken. Even after H.R. 3642 was introduced, congressional staff continued to discuss modifications to the authorities granted.

²⁵In the 102d Congress, S. 2135, the Food, Drug, Cosmetic and Device Enforcement Authorities Act was introduced in late November 1991, after hearings took place in the House Committee on Energy and Commerce. It contained many of the same provisions of H.R. 3642; however, it was different in scope from H.R. 3642. The Bush Administration and regulated industry also opposed this bill.

²⁶See CRS Rept. No. 92-102 SPR, FDA Enforcement: A Summary of H.R. 3642 and S. 2135, by Donna U. Vogt. Jan. 24, 1992.

CRS-17

PROPOSALS TO INCREASE FDA ADMINISTRATIVE ENFORCEMENT AUTHORITY FOR FOODS

FDA's consumer protection responsibilities have grown and evolved in the last decade; however, its power to enforce its varied mandates has not. Some Members in Congress would like to see FDA equipped with more administrative enforcement authority to reenforce FDA's authority over the industries it regulates. FDA's enforcement powers differ depending on the products it is regulating, and some congressional Members believe that such powers should be spread across the board or augmented with new authorities so FDA can regulate all the products it is responsible for in a consistent and unified manner. For example, FDA can itself seize counterfeit drugs but it cannot seize adulterated food without a formal seizure warrant from a judge. Critics contend that blanket augmentation of current FDA authority would not make food any "safer" and they claim that FDA is doing a very good job with the authority it now has. They argue that administrative authority without court supervision would be subject to potential abuse and misuse without any effective recourse.

On March 12, 1993, Dr. Kessler sent a memorandum to Donna Shalala, Secretary of Health and Human Services, stating that FDA would like the following statutory authorities to ensure safe food handling and preparation²⁷: records inspection; registration of food processors; requirement for HACCP systems (see below) for foods; presumption of interstate commerce; administrative civil money penalties; administrative temporary detention domestic authority; administrative recall authority; subpoena authority; authority to charge user fees for some food safety efforts; and authority to refuse entry on imported food where specific safety assurances from the foreign source are not met.

The following table lists a series of administrative enforcement tools that are of an "intermediate deterrent nature," and have been sought by FDA for the past several decades. The explanation of the tools is listed along with the rationale that has been set forth advocating these changes, as well as the criticism that has also been voiced against them.

²⁷David A. Kessler. Memorandum to the Secretary. U.S. Dept. of Health and Human Services. Subject: Food Safety Initiative--ACTION. March 12, 1993.

TABLE 4. FDA's Proposals For Expanded Administrative Enforcement "Tools"

Enforcement Tool	Rationale	Criticism
Records Inspection FDA inspectors would review and copy food producers sources, processing, and distribution records without violating business trade secrets.	FDA would use these records to control a problem product. Records would show where the problem came from and to whom the product was delivered.	Records inspection should only be by court order for serious problems, to prevent administrative abuse and misuse and to protect trade secrets.
Registration of Food Processors FDA would require registration to establish an inventory of food purveyors.	Through such a registration, FDA would get an accurate inventory of whom they were regulating.	Registration creates an enormous and ineffective burden for FDA and an unnecessary interference with business.
HACCP/Quality Assurance System FDA on January 21, 1994 proposed for notice and comment a mandatory system which would require that the seafood industry establish a Hazard Analysis Critical Control Point system. FDA could extend this plan to other facets of the food industry.	HACCP calls for a science-based analysis of potential hazards, determining where the hazards can occur in processing, instituting preventive measures to prevent problems, and taking corrective actions if they do occur. FDA saves money by monitoring HACCP records.	HACCP is already in existing FDA GMP regulations and is authorized by existing law. No new legislation is needed. FDA can adopt HACCP regulations where justified.
Presumption of Interstate Commerce FDA officials want to presume jurisdiction because most commerce involving food articles affect interstate commerce.	FDA could reduce its burden of proof before the courts and would no longer spend time and money processing records to prove to the courts that it had jurisdiction over a violative product.	FDA can easily prove its jurisdiction, and the issue is rarely contested, so new legislation is unnecessary.

TABLE 4. FDA's Proposals For Expanded Administrative Enforcement "Tools"

Enforcement Tool	Rationale	Criticism
Civil Money Penalties FDA wants to impose fines to seek punishment for offenders short of criminal action.	Such authority would allow FDA to take steps to "hurt the pocketbook" of the company in violation, particularly for acts which were committed without endangering public health, and after notice from FDA.	Such authority could easily be abused, especially if not imposed by a court after a full hearing. Existing sanctions are stringent and sufficient.
Temporary (Domestic) Detention Authority (Embargo) FDA inspectors want to detain suspected violative foods until the foods can be seized under a court's order.	This tool would help prevent the violative product from reaching consumers while seizure is being initiated.	Detention would put excessive power in administrative officials, which could easily be abused. Only a court should be allowed to do this and only for a few days.
Recall Authority FDA currently asks for "voluntary recalls." FDA wants authority to order recalls when firms refuse prompt, and effective voluntary recall.	No complaints would be filed with a court, and firms could defend their actions at an informal hearing. The voluntary recall process would remain as the initial recall approach.	The same criticism that only courts should have such power applies to recalls as to detention. Current FDA recall regulations work well.

TABLE 4. FDA's Proposals For Expanded Administrative Enforcement "Tools"

Enforcement Tool	Rationale	Criticism
<p>Subpoena Authority FDA would issue subpoenas to gather evidence and as part of administrative hearings in connection with a violation of the FFDCA.</p>	<p>Several other Federal regulatory agencies have such authority. FDA officials say that they have and will continue to abide by the law to protect the industry trade secret information (e.g., processing formulas), patient names, and other confidential information obtained as part of an investigation.</p>	<p>Administrative subpoena power would give unfettered discretion to FDA personnel. Only courts should have this enormous power. Companies will have no formal mechanism to object to a subpoena which is unduly burdensome or otherwise improper. Before records access is permitted, it must be subject to justification through judicial intervention, control and review.</p>
<p>User Fees Domestic and foreign industries including foods could pay for services provided by FDA. Examples include preparation of product certificates for export, providing electronic clearance of imports, and foreign inspections conducted by FDA.</p>	<p>User fees would help support FDA's costs for services benefitting regulated industry, e.g., product certificates, faster product clearance. Fees also would allocate resources more efficiently because FDA would place its resources where there is the greatest client demand.</p>	<p>User fees would constitute a direct Federal sales tax on all food products. User fees are not justified because FDA actions benefit the general public, not a particular company.</p>

TABLE 4. FDA's Proposals For Expanded Administrative Enforcement "Tools"

Enforcement Tool	Rationale	Criticism
Authority to Refuse Entry of Food Imports FDA wants to refuse foods offered for import where the food safety system of the country of origin is not equivalent to the U.S. system and food handlers have not registered with FDA. FDA has already proposed to implement HACCP for all U.S. seafood (domestic and imported) without new legislation. FDA also could act against products produced where there is no HACCP system or where FDA inspection of manufacturers has been refused.	This would enhance FDA's efforts to more effectively prevent entry into the United States of imported foods lacking assurance of safety.	Such treatment would greatly add to the cost of imported products, might be contrary to the new GATT agreement for lowering nontariff barriers, and could lead to retaliatory actions against U.S. products.

APPENDIX A. Federal Agencies Comparable Enforcement Authorities and Dates When Basic Authority was Granted.							
	USDA	CPSC	OHSA	EPA	DEA	NIH TSA	BATF
Records Inspection	1967	1972	1970	1988	1970	1966	N.A.
Temporary Detention (Embargo)	1967	N.A.	N.A.	1972	1970	N.A.	1958
Civil Money Penalties	N.A.	1972	1970	1978	1988	1966	1988
Recall	N.A.	1972	N.A.	1988	N.A.	1974	N.A.
Subpoena	1968	1972	1970	1986	1970	N.A.	1954

USDA=U.S. Department of Agriculture

CPSC=Consumer Product Safety Commission

OSHA=Occupational Safety and Health Administration

EPA=Environmental Protection Agency

DEA=Drug Enforcement Agency

NIHTSA=National Institute for Highways and Traffic Safety Administration

BATF=Bureau of Alcohol, Tobacco, and Firearms

N.A.=Not Applicable

Source: Food and Drug Administration. Office of Enforcement. Prepared by Joan Davenport. (301) 443-7400.

APPENDIX B. General FDA Enforcement Activities, Fiscal Years 1988-1993.						
	1988	1989	1990	1991	1992	1993
Inspections	19,192	17,740	16,811	18,609	17,064	17,315
Warning Letters*	450	370	498	832	1,564	1,755
Import Sample Examinations	37,923	44,936	41,108	42,200	50,382	42,758
Import Product Detention	25,456	25,740	26,393	27,298	41,155	33,088
Recalls	1,526	2,183	2,352	2,858	2,922	2,375
Seizures	196	144	144	168	183	117
Injunction Requests	17	13	9	21	31	23
Criminal Actions	24	16	19	43	52	26

*Two types of letters: "notices of adverse finds" or "regulatory letters" became "warning letters" on May 23, 1991.

Source: Food and Drug Administration. Office of Enforcement. Arvin P. Shroff, Deputy Director. (301) 443-7400.

CRS-24

APPENDIX C. 1990 Statement of Enforcement Policy United States Food and Drug Administration

The Food and Drug Administration (FDA), the nation's foremost line of consumer protection, is a scientifically-based law enforcement agency. The enforcement function of the FDA is two fold: to safeguard the public health, and to ensure honesty and fair-dealing between the regulated industry and consumers.

1. The FDA encourages and expects compliance with the laws and regulations it enforces. To this end the agency participates in cooperative and educational efforts designed to inform industry, health professionals, and the public of those legal requirements.
2. The FDA constantly conducts surveillance and investigations over the industry it regulates, to continuously assess compliance and discover noncompliance. Depending upon the nature of noncompliance, the FDA may afford an opportunity for correction by industry. If adequate correction does not occur within a reasonable period of time, the FDA is committed to swiftly initiate action to obtain compliance.
3. The FDA protects the public by relying on any and all of its varied enforcement tools--both administrative and judicial--according to the seriousness of the violation.
4. The FDA does not tolerate fraud, intentional violations, or gross negligence, and promptly seeks prosecution to punish and deter whenever appropriate.
5. The FDA uses fair and scientifically-sound law enforcement and regulatory work to assure efficiency in its enforcement activities and to maintain the public trust and confidence.
6. The FDA cooperates with, and enlists the cooperation of, other federal, State, and local agencies, and foreign governments and international organizations to extend the scope and increase the effectiveness of its consumer protection programs.
7. The FDA continuously evaluates its law enforcement programs and needs. It initiates administrative action and proposed legislative action--and it judiciously allocates resources--to enhance its ability to meet its law enforcement responsibilities within its budget and priorities.

Ronald G. Chesemore
Associate Commissioner
for Regulatory Affairs
1985 - Present

James S. Benson
Acting Commissioner
of Food and Drugs

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Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States

House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee

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May 20, 1994

WRM

MEMORANDUM

TO: Members of the Subcommittee on Human Resources and
Intergovernmental Relations

FROM: Edolphus Towns, Chairman

RE: Hearing: "Reinventing the Federal Food Safety System: Review of FDA's
Food Safety Programs," Wednesday, May 25, 1994, at 9:30 a.m., 2247 RHOB

I. INTRODUCTION

As you know, last fall the Subcommittee began reviewing the Federal government's food safety programs in light of the Vice President's recommendation to consolidate such programs within the Food and Drug Administration (FDA). The Subcommittee's initial hearings on the U.S. Department of Agriculture's (USDA) meat and poultry inspection program last November 4 and 19 revealed dangerous flaws in USDA's programs and an inherent conflict of interest in USDA's mission (see my memoranda of Nov. 1 and Nov. 16). We will review FDA's food safety programs during this hearing.

II. BACKGROUND

FDA is responsible for ensuring that all foods in interstate commerce (except meat and poultry) are not contaminated or otherwise adulterated, are produced under sanitary conditions, and are not misbranded or deceptively packaged. Although FDA must approve certain food ingredients, such as food additives, before they may enter the market (premarket approval), almost all food products may be marketed without FDA's premarket approval and are subject to FDA's monitoring and surveillance only after they have entered the market (postmarket surveillance). To conduct postmarket surveillance, FDA (1) inspects domestic food establishments (e.g., manufacturing and processing facilities) to ensure compliance with federal laws, regulations, and good manufacturing practices, and (2) inspects imported food products at the port of entry to ensure compliance with the same safety and labeling requirements established for domestic foods. Some inspections are carried out by the States under contract with FDA.

The Nation's consumers rely on FDA to oversee the industry and ensure the safety of about \$240 billion worth of domestic foods and about \$15 billion worth of imported foods. FDA is responsible for overseeing about 260,000 separate classes of food products and about 10,000 new products enter the market each year. In addition, although subject to FDA jurisdiction, about 537,000 commercial restaurants, 172,000 institutional food programs, 190,000 retail food stores, and 1.5 million food vending locations submit to State and local health department inspections. FDA is also responsible for policing both domestic and imported foods for excess pesticide and other chemical residues.¹

In fiscal year 1993, FDA devoted about 2,700 staff years and \$205 million to food safety activities.² The Center for Food Safety and Applied Nutrition (CFSAN) with field assistance from the Office of Regulatory Affairs is primarily responsible for food regulation within FDA.

III. RELEVANT LAWS

Federal Food, Drug, and Cosmetic Act, as amended (FFDCA) (21 U.S.C. 301 *et seq.*) (Other relevant laws include, the Public Health Service Act, Pesticide Monitoring Improvement Act of 1988, Egg Products Inspection Act, Safe Drinking Water Act, Federal Anti-Tampering Act, and Federal Import Milk Act)

IV. PURPOSE OF THE HEARING

The purpose of this hearing is to review FDA's food safety programs in light of the Vice President's recommendations to consolidate all Federal food safety programs within FDA. Because most food products are not subject to FDA premarket approval, the hearing is focused on FDA's postmarket surveillance and monitoring efforts to ensure the safety of domestic and imported food. Because of the broad scope of food products subject to FDA jurisdiction, the hearing is also targeted to FDA's efforts to ensure the safety of seafood and to deal with microbial contamination of food.

V. WITNESSES

The Subcommittee invited the following witnesses to present testimony:

The Honorable Al Gore, Jr., Vice President of the United States
 The Honorable Donna Shalala, Secretary of Health and Human Services
 The Honorable Charles A. Bowsher, Comptroller General, U.S. General Accounting Office
 Jack Guzewish, Chief Sanitarian, New York State Department of Health
 Dr. Gary Hlady, Epidemiologist, State of Florida
 Dr. Peggy M. Foegeding, Professor, Food Science and Microbiology, North Carolina State University

Caroline Smith DeWaal, Public Voice
 Juanita Duggan, National Food Processors Association
 Sherwin Gardner, Grocery Manufacturers Association
 Lee Weddig, National Fisheries Institute

NOTE: Dr. Fred Shank, Director, CFSAN, FDA, will be testifying on behalf of HHS and John Harman, Director, Food and Agriculture Issues, RCED/GAO, will be testifying on behalf of GAO. The Vice President's office has informed us that the Vice President is not available to present testimony. His office has not yet identified who will be testifying on his behalf.

The Subcommittee also invited the following individuals and organizations to provide written statements for the record:

New York's Seafood Council
 Animal Health Institute
 Food Marketing Institute
 National Restaurant Association
 Luther C. McKinney, Senior Vice President for Law and Corporate Affairs, Quaker Oats Company
 Dr. Michael T. Osterholm, State Epidemiologist, Minnesota Department of Health

VI. MAJOR ISSUES

A. New Food-borne Threats

The current Federal food safety system is obsolete because it has failed to keep pace with changes in new food-borne threats. Specifically, dramatic changes in the type, source and distribution of food; new food technologies; consumer behavior and demographics; and emerging microbial pathogens have occurred since FFDCA was enacted in 1938. For example, more people consume commercially processed or commercially prepared foods than 56 years ago. According to FDA, consumer demand for "fresh" foods in convenient, ready-to-cook or eat forms has fostered the development of sophisticated processing and packaging systems that can significantly extend the shelf life of foods. In addition, almost half of the money consumers spend on food now goes to meals and snacks away from home. However, these new food products and packages and new patterns of distribution and consumption are raising new food safety concerns.

Chief among these concerns is the increasing number of new food pathogens.³ Most people have heard of salmonella. But scientists have lately identified other harmful microorganisms, such as *Listeria monocytogenes*, *Campylobacter jejuni*, *E. coli* 0157:H7, Norwalk virus, and *Vibrio* spp., as important foodborne pathogens. That is partly because scientists have better ways of detecting microbes, but it also reflects trends in food processing and distribution that leave products vulnerable in new ways.⁴ For

example, we depend on refrigeration to keep food safe in transport, but the *listeria* bacterium can survive refrigeration. Each year, listeriosis strikes about 1,850 Americans; nearly one-fourth of those people die.⁵

Of the various sources of food contamination, harmful microbes in food cause almost all cases of acute foodborne illness in the United States, according to food scientists. In fact, **food-borne disease** continues to be a major and **growing public health problem** in the United States that is preventable, according to the Centers for Disease Control and Prevention (CDC).⁶ Each year food-borne disease kills at least **9,100** people while another **6.5 million** become sick, according to CDC. Because many cases go undiagnosed and unreported, the true extent of food-borne illness in the United States is probably much higher—80 million by one estimate.⁷ Food-borne disease particularly harms infants, children, the elderly and immunocompromised individuals. In addition, the social costs of food-borne illness, such as medical expenses and lost productivity, are estimated to reach between \$4 billion and \$8 billion annually.⁸

B. Seafood safety

Seafood poses special challenges in ensuring its safety. First, unlike most meat and poultry, seafood is still mostly a wild-caught flesh food that is harvested under very different conditions and at varying distances from processing, transport, and retail facilities. Second, there are over 350 commercially marketed species. Third, no other flesh food is imported in the quantity, or from as many countries as seafood. According to FDA, over 55 percent of seafood consumed in the United States is imported from about 135 countries. Fourth, a lot of seafood is consumed from recreational sources. FDA estimates that recreational fishing contributes 4 pounds beyond the 15 pounds of seafood consumed per capita from commercial channels.

According to the National Academy of Sciences (NAS), "Most seafood available to the U.S. public are wholesome and unlikely to cause illness in the consumer."⁹ According to CDC, seafood accounted for 20% of foodborne disease outbreaks between 1973 and 1991, compared with 8% for beef, 7% for poultry, and 1% for eggs. However, because most outbreaks attributed to seafood involved fewer persons than those due to other foods, seafood accounted for only 5% of all reported foodborne cases, compared to 10% for poultry, 9% for beef, and 2% for eggs.¹⁰ Although significant limitations in CDC's data preclude definitive conclusions about the relative safety of seafood-borne illness, CDC, NAS, FDA, and others believe that data are fairly consistent in showing that seafood overall is as safe or safer than other flesh foods in terms of frequency of illness.

"Nevertheless, there are areas of risk," according to NAS. The major risk of disease is associated with molluscan shellfish (e.g., oysters, clams, and mussels) consumed raw or partially cooked and from two natural toxins, ciguatoxin and scombrototoxin, which occur in certain species of finfish.¹¹ In fact, a 1991 FDA/CDC risk assessment

concluded that the risk of illness associated with molluscan shellfish consumed raw or partially cooked is greater than for any cooked flesh food. Other seafood safety concerns include viruses, parasites, chemical contaminants (e.g., mercury, PCBs, dioxin, pesticides, animal drugs), and decomposition.

1. Vibrio vulnificus in raw oysters

One example of foodborne disease associated with the consumption of raw shellfish is *Vibrio vulnificus* infections associated with raw oyster consumption. *V. vulnificus* is a naturally occurring bacterium commonly found in the coastal waters of the Gulf of Mexico that contaminates oysters and other shellfish. Some studies report that almost 100% of oysters harvested from these waters, especially during warm weather months, harbor *V. vulnificus*. Although NAS reported that *V. vulnificus* infections are relatively uncommon, the bacterium is extremely dangerous for people in certain high-risk groups, such as those with preexisting liver disease or compromised immune systems. When such persons become infected, the mortality rate can exceed 50 percent.¹² In 1993, the State of Florida estimated that based on the number of *V. vulnificus* cases reported and consumer survey data of raw oyster consumption, the annual rate of illness from *V. vulnificus* infections for adults with liver disease who ate raw oysters was 72 per 1 million adults and the death rate was 45 per 1 million.¹³

According to NAS, "Thorough cooking of seafood products would virtually eliminate all microbial and parasitic pathogens. Individuals who choose to eat raw seafood should be educated about the potential risks involved and how to avoid or mitigate them. In particular, immunocompromised individuals and those with defective liver function should be warned never to eat raw shellfish."¹⁴

Despite the risks associated with *V. vulnificus* in raw oysters, FDA has not set acceptable limits for this bacterium in raw oysters and does not regularly monitor levels of *V. vulnificus* in harvested shellfish. (FDA is convening a workshop in June to address these issues.) In 1991, Public Voice petitioned FDA to require a mandatory warning label on all raw shellfish to educate consumers about the risks associated with the consumption of raw shellfish. FDA has not required such a label. However, FDA has recommended that the States adopt a point-of-sale information statement for use in educating consumers about the hazard involved in consuming raw oysters. In addition, several states (e.g., California, Louisiana, Florida) have required warning of raw oysters aimed at providing consumers with risk information.

2. Federal seafood safety programs

FDA's seafood safety program budget increased from about \$25 million in FY 1990 to about \$41 million in FY 1992 (funding remained level for FY 1993). In addition, FDA created the Office of Seafood in February 1991.

Although FDA is the primary Federal agency responsible for ensuring the safety of seafood, three other Federal agencies and an intergovernmental commission are involved. The National Marine Fisheries Service within the Department of Commerce conducts a voluntary, fee-for-service program aimed at quality and wholesomeness. The Environmental Protection Agency regulates contaminant levels and monitors the purity of water from which fish and shellfish are harvested. CDC collects and reports on foodborne disease outbreak data associated with seafood. Lastly, the Interstate Shellfish Sanitation Conference (ISSC), is a cooperative program in which FDA, State officials, and the shellfish industry work to control the quality and safety of oysters, clams, and mussels sold in interstate commerce.

C. FDA's Inspection Program Is Obsolete

FDA's current inspection program cannot ensure the safety of the nation's food supply because it is obsolete, ineffective and inefficient. First, the sheer size and diversity of the Nation's food supply and its increasingly complex distribution system overwhelm FDA's capacity to inspect food and food facilities for compliance. For example, due in part to resource constraints, FDA inspects the nation's approximately 50,000 domestic food establishments (e.g., manufacturers, processors, and warehouses), on average, once every eight years and that number is declining. The number of FDA food safety inspections has been reduced by two-thirds in the past twelve years, from 20,500 conducted in 1981 to about 6,600 in 1993. Furthermore, FDA inspects less than eight percent of the over one million entries of food imports per year. Second, FDA's inspections can only determine the adequacy of conditions in a food plant at the time of the inspection but not whether the company regularly produces food in a safe manner. Third, although FDA samples and tests food products for contamination, such as pesticides and pathogenic bacteria, FDA simply does not have the resources to inspect, sample and analyze more than a very small percentage of the food supply. Fourth, such an approach places the burden on the Federal government to ferret out problems rather than on the regulated industry to affirmatively establish the safety of food products. At best, FDA's inspection program can only react to problems, it cannot prevent problems.

To its credit, FDA has recognized the inherent limitations in its current inspection program and proposed a major new food safety initiative. Specifically, on January 21, 1994, FDA proposed a mandatory Hazard Analysis Critical Control Point (HACCP) system to ensure the safety of all seafood.¹⁵ HACCP is an approach that attempts to identify and analyze likely hazards in a production process and then control these hazards at critical points in the process to prevent them from occurring. NAS, GAO, and many others have urged FDA and USDA to adopt HACCP approaches to better ensure food safety. The comment period on FDA's proposed rule expires later this month. Implementation is projected in 1995.

The Subcommittee has obtained internal documents which show that FDA planned to issue an Advance Notice of Proposed Rulemaking to invite comments on

extending HACCP requirements to all other food products at the time it issued the proposed seafood HACCP guidelines. However, it appears that OMB recommended that FDA promulgate the seafood regulations first before extending the program to other food commodities. Consequently, all other food products (except low-acid canned food and infant formula) are still subject to FDA's obsolete inspections.

Although HACCP is widely supported as an approach to food safety assurance, some critics are concerned that FDA's proposal for seafood is only a paper tiger because FDA will still lack the resources to fully verify the integrity of HACCP plans at individual facilities, especially for foreign facilities. Furthermore, some believe the proposal represents nothing more than an industry honor system because FDA will shift from inspecting products to reviewing a firm's paperwork with little knowledge of the validity and integrity of the documents. FDA disputes these claims. The Subcommittee has requested but not yet received documents from FDA on how it will verify HACCP plans at individual facilities and its resource estimates for implementing the seafood HACCP proposal.

In December, 1993, FDA also published the latest version of the Model Food Code, designed to help State and local governments prevent foodborne diseases. According to FDA, the Model Food Code outlines the practices for safe food handling at the retail level.

D. Limitations in FDA's Enforcement Authority

FDA, GAO, and many others have determined that FDA has less authority to regulate foods than it does for drugs and medical devices.¹⁶ In particular, FDA generally cannot

- presume that food firms are engaged in interstate commerce,
- require food firms to register with the agency,
- obtain access to manufacturers' production and distribution records,
- impose civil penalties for violations, or
- detain domestic products that violate food safety standards without either obtaining a firm's voluntary cooperation or a court order.¹⁷

The Vice President's National Performance Report suggests that the new FDA envisioned would have additional authority in some of these areas. Expanding FDA's enforcement authority for foods has been controversial and the subject of much congressional debate. The Subcommittee has requested the Congressional Research Service to summarize past recommendations and deliberations on this issue and will be releasing the report at the hearing.

ENDNOTES

1. Statistics are from "Food Expenditures and Food Regulation: Putting Regulation in Perspective" (unpublished FDA report, 1991); Comprehensive Needs Assessment: 1994-1997 (FDA, Department of Health and Human Services, 1990); "Regulatory Impact Analysis of the Proposed Rules to Amend the Food Labeling Regulations," Federal Register 56, Nov. 27, 1991; Food Safety and Quality: Who Does What in the Federal Government (GAO/RCED-91-19A&B, Dec. 21, 1990); and FDA 2000 Building for the Future--DRAFT (FDA, May 6, 1994).

2. Justification of Estimates for Appropriations Committees for Fiscal Year 1995 (Dept. of Health and Human Services, Vol XII (FDA), 1994), p. 37.

3. Presentation by Dr. Stanford Miller, University of Texas Health Science Center, before a workshop sponsored by The Food Forum, "Prioritizing, Managing and Communicating Food Safety Risks: Dealing With What Bugs Us," Food & Nutrition Board, Institute of Medicine, National Academy of Sciences, Washington, DC, Sept. 14, 1993.

4. Kristine L. MacDonald and Michael T. Osterholm, "The Emergence of *Escherichia coli* 0157:H7 Infection in the United States," JAMA (May 5, 1993, vol. 269, no. 17), p. 2265. See also, Emerging Infections: Microbial Threats to Health in the United States (Washington, D.C.: National Academy Press, 1992).

5. Anne Schuchat et al., "Role of foods in Sporadic Listeriosis, I: Case-control Study of Dietary Risk Factors," Journal of the American Medical Association, April 15, 1992, pp. 2041-2045.

6. Written testimony of Dr. Paul Blake, Chief of the Enteric Diseases Br., Division of Bacterial and Mycotic Diseases, CDC, Feb. 5, 1993, Hearing, Subcommittee on Agricultural Research, Conservation, Forestry, and General Legislation, Senate Committee on Agriculture, p. 48. See also testimony of Dr. James Hughes, Director, National Center for Infectious Diseases, CDC, March 16, 1993, Joint Hearing, Subcommittee on Department Operations and Nutrition and Subcommittee on Livestock, House Committee on Agriculture, p. 87.

7. Douglas L. Archer and John E. Kvenberg, "Incidence and Cost of Foodborne Diarrheal Disease in the United States," Journal of Food Protection 48 (1985), pp. 887-894.

8. Tanya Roberts and David Smallwood, "Data Needs to Address Economic Issues in Food Safety," American Journal of Agricultural Economics, Aug. 1991, p. 935.

9. Ahmed, F.E. ed., Committee on Evaluation of the Safety of Fishery Products, Food and Nutrition Board, Institute of Medicine, NAS, Seafood Safety (National Academy Press, 1991), p. 1.

10. Written statement of Paul Blake, M.D., Chief, Foodborne and Diarrheal Diseases Branch, CDC, before the Subcommittee on Fisheries Management, House Committee on Merchant Marine and Fisheries, June 23, 1993, p. 6.

11. Written statement of Thomas Billy, Director, Office of Seafood, FDA, before the Subcommittee on Fisheries Management, House Committee on Merchant Marine and Fisheries, June 23, 1993, p. 5-6.

12. NAS, Seafood Safety, p. 41.

13. "Vibrio vulnificus Infections Associated with Raw Oyster Consumption--Florida, 1981-1992," Morbidity and Mortality Weekly Report, CDC, June 4, 1993, pp. 405-407.

14. NAS, p. 7.

15. "Proposal to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products," Federal Register, vol. 59, Jan. 28, 1994, p. 4142.

16. For example, see, Memorandum from David Kessler, Commissioner, FDA, to the Secretary, HHS, "Food Safety Initiative--Decision," March 31, 1993, in subcommittee's files.

17. See GAO's Uniform, Risk-based Inspection report at p. 28.



DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD, DRUG SERVICE

Food and Drug Administration
Rockville MD 20857

March 12, 1993

MEMORANDUM TO THE SECRETARY

THROUGH: DS _____
 COS _____
 ES _____
 Acting ASH _____

SUBJECT: Food Safety Initiative--ACTION

PURPOSE

During the recent budget briefings, I mentioned the urgent need for a comprehensive Federal policy for food safety. This memorandum is intended to explain that concept in more detail, and to request a briefing with you on this subject as soon as possible.

INTRODUCTION

The Food and Drug Administration is the lead food safety agency within the Federal government, through its enforcement of the broad food safety provisions of the Food, Drug, and Cosmetic Act of 1938.¹ Although Theodore Roosevelt spurred passage of the first Federal food law in 1906², that law was "updated" in 1938 to form the current food statute, whose provisions have remained essentially unchanged since enactment.

The food supply, however, has changed dramatically since 1938. Food technology has become "high tech;" food processing operations are increasingly large scale and centralized; and market-driven innovations in product formulation, processing and packaging have vastly increased the sheer number of food products FDA regulates. Food consumption patterns are also different, with, for example, the great increase in restaurant consumption.

¹Of course, there are other significant agencies involved in food safety--USDA regulates meat and poultry, CDC carries out the Federal government's epidemiological surveillance, EPA approves pesticides for use on food crops, and the National Marine Fisheries Services regulates seafood in conjunction with FDA.

²The Pure Food and Drug Act created FDA's forerunner in the Agriculture Department to regulate most foods; the Meat Inspection Act gave authority over meat and poultry to another part of USDA. FDA was given its current name in 1930 and was transferred to HHS' predecessor Department in 1940.

Page 2 - The Secretary

Accompanying these changes in food processing and consumption has been a rise in foodborne illnesses, caused by many factors (e.g., new pathogens, changes in food handling, increased transport of food over long distances, environmental pollution and increased use of chemicals that can contaminate foods). Finally, unlike in the pre-World War II era, many foods are today imported from other countries, whose food safety standards are in some cases inadequate to ensure that foods are protected from contamination.

In the years since the Act's enactment, food safety has been a potent issue in this country. In the 1950s there was great public concern about pesticide and food additive use, culminating in amendments to the Food, Drug and Cosmetic Act authorizing FDA to set limits on pesticides and to approve food additives (and leading the Eisenhower Administration to double FDA's staff). Publication in 1962 of Rachel Carson's bestseller Silent Spring generated great consumer anxiety about pesticides, and prompted the Kennedy Administration to again increase FDA's size.

Throughout the 1970s and 80s there were periodic public scares about food contaminations. Many have been "false alarms" (such as the Alar in apples incident) that have obscured the very real threats to food, usually caused by microbiological agents that take advantage of inadequate quality control procedures.

Despite the many years of growth and change in the food supply, the statutory structure for ensuring food safety has remained essentially unchanged since 1938. Over the years piecemeal amendments have been made to solve individual problems, creating a patchwork of statutory directions. We believe it is now time to prepare the food supply for the 21st century by modernizing our food safety legislation and the regulatory system.

THE SCOPE OF THE FOOD SAFETY HAZARDS

The term "food safety" has been used generically for years to cover a number of problems related to food and health. It includes, for both domestically-produced and imported foods, issues such as the following:

- o Foodborne biological hazards such as salmonella in eggs, Listeria in dairy products, cholera in shellfish, E. coli in meat, and many other pathogens that threaten health;
- o Chemical contaminants, such as heavy metals and pesticides (both those registered by EPA for agricultural use and ones of public health concern that are persistent environmental contaminants, e.g., lead);
- o Natural contaminants, such as aflatoxin, a carcinogen that is often found in grain and peanuts;

Page 3 - The Secretary

- o Drug residues in animal products for human consumption, such as antibiotics in milk or meat;
- o New foods made using biotechnology that will change the nature of food we consume in the years ahead;
- o New food components, such as the "fake fat" Olestra that we are now reviewing for marketing approval, that will have major impacts on dietary practices if approved.
- o Improper consumer preparation of foods, which is the most common cause of foodborne illness (such as chopping salad ingredients on a cutting board after using the board to prepare raw chicken); and
- o New food processing and packaging techniques that will make substantial contributions to food storage and consumer convenience, yet will also challenge both the food industry and FDA scientists to understand their possible effects upon health (e.g., the effects of microwaving on food packaging).

THE COSTS OF FAILURE TO SOLVE THE PROBLEM

As well meaning as attempts in recent years have been to address the food safety dilemma, there remains much room for improvement. The public continues to have high expectations for the performance of food safety regulatory agencies and the U.S. continues to face a significant public health threat from foodborne illness. Witness, for example:

- o CDC estimates that over 9,000 people die each year from foodborne illness, caused principally by microbiological contamination (although least often from commercially processed foods).
- o A recent study by FDA's Center for Food Safety and Applied Nutrition estimated that there are at least 24 million, and perhaps as many as 81 million, cases of foodborne illness per year.
- o The health care costs associated with foodborne illness are enormous. One estimate of the annual costs associated with one common pathogenic illness, salmonellosis, is about \$2 billion, and total costs of foodborne illnesses are probably well over \$10 billion per year.³

³Because disease from foodborne sources is generally preventable, any resources spent on prevention-related research, surveillance and public education would be only a fraction of the cost otherwise borne by the economy when disease occurs.

Page 4 - The Secretary

- o USDA is now reporting to us about 6,000 cases each year of improper drug residues in meat and poultry (USDA regulates the meat; FDA regulates the use of drugs in food-producing animals).
- o The safety of fish and other seafood is increasingly questioned by consumer groups and Congress, and calls have been made to move seafood regulation to USDA. [The safety of meat is also being questioned, and there are calls to transfer meat regulation to FDA or an independent food agency.]
- o Imports of foods from other countries are growing rapidly, now up to over 2 million "entries" per year, posing an ever-increasing challenge to our ability to ensure that those foods are safe and wholesome. In fact, we can only inspect under 10 percent of food imports and, of those inspected, thousands must be "detained" as being in violation of our standards.
- o The cumulative effect of years of exposure to pesticides and other chemical contaminants is uncertain, but public concern about those food contaminants has remained high for a generation.
- o Hardly a month goes by in which there is not a public scare over the latest contaminant in food -- Alar in apples, aldicarb in watermelon, EDBC in flour, PCBs in fish, lead in ceramicware, cholera in shellfish, dioxin in food packaging, salmonella in eggs, Listeria in cheese, and more (many of which are not a true health problem, but are perceived as such by the public). The E. Coli incident in Washington is only the latest in a long series.

WHAT IS NEEDED TO SOLVE THE PROBLEM

Years of experience with foodborne public health threats and with regulation of the food supply, as well as numerous public and private reports on food safety, have suggested that there are additional steps that may be appropriate to adequately ensure the safety of our Nation's food supply, including:

- 1) A Uniform National System of Food Safety Assurance - We need to consider whether to mandate that all segments of the food industry subscribe to a comprehensive food safety assurance program which would govern the handling, processing, transportation, and preparation of food; and that would focus on the areas where we know food is most likely to become contaminated or otherwise threatened (e.g., adequate refrigeration in holding and shipment; adequate protection from chemical contaminants, pests, and pathogens;

Page 5 - The Secretary

adequate handling and cooking during processing). If implemented, this should comprise a coordinated regulatory framework encompassing the states, HHS, USDA, and other agencies concerned about food safety.

- 2) Authority to Protect the Public - FDA lacks many of the modern enforcement tools available to virtually all other Federal regulatory agencies. For example, the agency is not authorized to detain a contaminated product, cannot require food firms to register, cannot inspect the records of a food processor, and cannot order a recall of a product known to pose a health threat.
- 3) Inspection and Sampling - While the food industry has grown enormously in recent years, and imported foods have increased substantially, FDA's inspectional resources have been reduced. We do not have the resources to inspect many food processing facilities regularly (on average, every eight years), and inspect only a tiny fraction of imported foods.
- 4) Other Needs - There is great need for additional research into the nature and biological action of pathogens, for better analytical methods to test for the presence of chemical and biological contaminants, and for more training for the state, local, and Federal inspectors who are charged with identifying such threats.

THE FOOD SAFETY INITIATIVE

Despite the years of public disagreement about how to resolve the food safety problems, I believe that the basis for a new program exists that can have an enormously beneficial impact on health with little or no additional taxpayer funding. Our current thinking involves three principal elements to strengthen FDA's role in improving food safety. These elements can be summarized as follows:

Regulations to Ensure Quality Control

We should consider the need for new regulations that would require food producers, processors, transporters and retailers to prepare plans for controlling hazards within their operations. If promulgated, these regulations could be based on the proven concept of "HACCP"--Hazard Analysis Critical Control Points--which focuses on critical points in food processing that might permit food to become contaminated. The regulations could be tailored to each segment of industry, yet be national in scope to ensure consistent, uniform protection of the food supply. We

Page 6 - The Secretary

believe we could build strong industry support for a widespread HACCP program. In fact, we are working now with the National Fisheries Institute (the industry trade association) on a mandatory HACCP program for seafood processors that will greatly improve seafood safety.

New Statutory Authority to Control Food Hazards

We should examine what new authorities are needed to ensure safe food handling and preparation, for example:

- to require producers to register their facilities, so that we know by whom food is being produced;
- to authorize FDA to require that all food producers, transporters, and retailers establish and maintain a comprehensive program to ensure the safety of the foods they handle;
- to authorize FDA to refuse entry to food imports where the food safety inspection system of the originating country is not equivalent to the U.S. system and the food handler has not registered with FDA, does not have a HACCP program, or has refused FDA access to inspect the manufacturing facility.
- to permit an inspector to review a food producer's processing records;
- to authorize FDA inspectors to detain a suspect food until its safety can be determined;
- to allow FDA to order the recall of a food found to be hazardous to health;
- to give FDA the flexibility to seek punishment for offenders short of criminal action, that is, to impose civil penalties as an intermediate deterrent;
- to authorize the collection of user fees for some of FDA's food safety efforts, as described below.

Increased Resources to Protect the Food Supply

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. Indeed, as one comparison, USDA has 9000 employees devoted to the inspection of meat and poultry, while FDA has 770 for the entire rest of the food supply. We need to increase domestic inspections, import coverage, and other related activities such as HACCP development, research, and methods development. We are now

Page 7 - The Secretary

examining those needs in detail so as to arrive at estimates of their likely costs.

HOW CAN FOOD SAFETY IMPROVEMENTS BE FUNDED?

I am keenly aware of the limitations on new funding for any Federal program. However, I believe we can develop a strategy that accomplishes our goals without seeking new appropriations.

First, there are areas of food protection that are appropriate for user fees. Last year the drug industry agreed to support user fees for increased FDA resources for drug reviews. That program promises to significantly reduce the time it takes to get new therapies on the market. In the food safety area, there are three sources of user fees that I recommend we consider--import examination, export certification, and establishment registration. Imposing an import fee merely requires that foreign importers pay for FDA to ensure that their foods are of sufficient quality to enter the United States. Export certification is a service provided to American exporters that provides a significant benefit to those exporters, by certifying to foreign governments that an American food export would be of acceptable quality in this country. Establishment registration is merely a fee to register a food processing facility with the FDA. We believe all of these fees can be designed to generate sufficient funds without creating an undue burden on food production or international trade.

In addition to funding, we may be able to greatly enhance the use of existing resources with more modern inspection and enforcement powers. In addition, the states have food safety programs, and it should be possible to design programs in which Federal and state officials ensure against duplication of effort while also improving coverage of the food supply.

Finally, USDA has substantial numbers of employees nationwide involved in all aspects of food production and marketing--not only meat inspection, but also insect control, land management on farms, grading of agricultural products, and other agriculture related activities. I recommend that we approach Secretary Espy about factoring joint HHS-USDA food safety protections into his comprehensive review of USDA's organization and mission. Indeed, we understand that Mr. Espy has meat and poultry safety high on his list of priorities, and intends to seek a meeting with you to discuss food safety. The Centers for Disease Control should be a part of any such discussions, as their role in epidemiological surveillance and disease prevention is an important part of protecting the public from unsafe foods.

Page 8 - The Secretary

RECOMMENDATION

I believe that food safety reform is essential to carrying out FDA's mission of protecting the food supply and the public health. It will have the ancillary benefits of strengthening the integrity (and thus competitiveness) of American agricultural exports and of lowering health care costs. I recommend that we brief you and your senior staff on these concepts as soon as possible, with the goal of announcing a comprehensive legislative/regulatory food safety plan this spring.

DECISION

Schedule a briefing with FDA officials as soon as possible.

Concur _____ Nonconcur _____ Date _____

A handwritten signature in dark ink, appearing to read 'D. A. Kessler', followed by a small flourish.

David A. Kessler, M.D.
Commissioner of Food and Drugs



DEPARTMENT OF HEALTH & HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
Rockville MD 20857

March 31, 1993

MEMORANDUM TO THE SECRETARY

THROUGH: DS _____
 COS _____
 ES _____
 Acting ASH *Andrew F. Morley / T. Iteilaq*

SUBJECT: Food Safety Initiative--DECISION

PURPOSE

During the recent budget briefings, I mentioned the urgent need for a comprehensive Federal policy for food safety. This memorandum is intended to explain that concept in more detail, and to recommend that the Department embark upon such an initiative as soon as possible.

INTRODUCTION

The Food and Drug Administration is the lead food safety agency within the Federal government, through its enforcement of the broad food safety provisions of the Food, Drug, and Cosmetic Act of 1938.¹ Although Theodore Roosevelt spurred passage of the first Federal food law in 1906, that law was "updated" in 1938 to form the current food statute, whose provisions have remained essentially unchanged since enactment.

The food supply, however, has changed dramatically since 1938. Food technology has become "high tech;" food processing operations are increasingly large scale and centralized; and market-driven innovations in product formulation, processing and packaging have vastly increased the sheer number of food products FDA regulates. Food consumption patterns are also different, with, for example, the great increase in restaurant consumption.

¹Of course, there are other significant agencies involved in food safety--USDA regulates meat and poultry, CDC carries out the Federal government's epidemiological surveillance, EPA approves pesticides for use on food crops, and the National Marine Fisheries Service oversees seafood in conjunction with FDA.

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Page 2 - The Secretary

Accompanying these changes in food processing and consumption has been a ~~rise in foodborne illnesses~~, caused by many factors (e.g., new pathogens, changes in food handling, increased transport of food over long distances, environmental pollution and increased use of chemicals that can contaminate foods). Finally, unlike in the pre-World War II era, many foods are today ~~supported~~ from other countries, whose food safety standards are in some cases inadequate to ensure that foods are protected from contamination.

In the years since the Act's passage, food safety has been a potent issue in this country. In the 1950s there was great public concern about pesticide and food additive use, culminating in amendments to the Food, Drug and Cosmetic Act authorizing FDA to set limits on pesticides and to approve food additives (and leading the Eisenhower Administration to double FDA's staff). Publication in 1962 of Rachel Carson's bestseller Silent Spring generated great consumer anxiety about pesticides, and prompted the Kennedy Administration to again increase FDA's size.

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Despite the many years of growth and change in the food supply, the statutory structure for ensuring food safety has remained essentially unchanged since 1938. Over the years piecemeal amendments have been made to solve individual problems, creating a patchwork of statutory directions. ~~We~~ we believe it is now time to prepare the food supply for the 21st century by modernizing our food safety legislation and the regulatory system.

THE SCOPE OF THE FOOD SAFETY HAZARDS :

The term "food safety" has been used generically for years to cover a number of problems and challenges related to food and health. It includes, for both domestically-produced and imported foods, issues such as the following:

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- o Natural contaminants, such as aflatoxin, a carcinogen that is often found in grain and peanuts;

Page 3 - The Secretary

- o ~~new~~ residues in animal products for human consumption, such as antibiotics in milk or meat;
- o ~~new~~ foods made using ~~biotechnology~~ that will change the nature of food we consume in the years ahead;
- o ~~new~~ food components, such as the "fake fat," Olestra, that we are now reviewing for marketing approval, that will have major impacts on dietary practices if approved.
- o ~~Improper~~ consumer preparation of foods, which is the ~~most~~ common cause of foodborne illness; (such as chopping salad ingredients on a cutting board after using the board to prepare raw chicken); and
- o ~~The~~ food processing and packaging techniques that will make substantial contributions to food storage and consumer convenience, yet will also challenge both the food industry and FDA scientists to understand their possible effects upon health (e.g., the effects of microwaving on food packaging).

THE COSTS OF FAILURE TO SOLVE THE PROBLEM

As well meaning as attempts in recent years have been to address the food safety dilemma, there remains much room for improvement. The public continues to have high expectations for the performance of food safety regulatory agencies and the U.S. continues to face a significant public health threat from foodborne illness. Witness, for example:

- o CDC estimates that over 9,000 people die each year from foodborne illness, caused principally by microbiological contamination (although least often from commercially processed foods).
- o A recent study by FDA's Center for Food Safety and Applied Nutrition estimated that there are at least 24 million, and perhaps as many as 81 million, cases of foodborne illness per year.
- o The health care costs associated with foodborne illness are enormous. One estimate of the annual costs associated with one common pathogenic illness, salmonellosis, is about \$2 billion, and total costs of foodborne illnesses are probably well over \$10 billion per year.

³ Because disease from foodborne sources is generally preventable, any resources spent on prevention-related research, surveillance and public education would be only a fraction of the cost otherwise borne by the economy when disease occurs.

Page 4 - The Secretary

- o USDA is now reporting to us about 6,000 cases each year of improper drug residues in meat and poultry (USDA regulates the meat; FDA regulates the use of drugs in food-producing animals). This has been exacerbated by greater concentrations of producers in recent years, which has led to more extensive spread of disease and drug use in herds and flocks.
- o The safety of fish and other seafood is increasingly questioned by consumer groups and Congress, and calls have been made to move seafood regulation to USDA. [The safety of meat is also being questioned, and there are calls to transfer meat regulation to FDA or an independent food agency.] Also, new drug residue concerns in seafood are emerging from the rapid growth in aquaculture (in which farm-raised fish are given drugs with their feed).
- o Imports of foods from other countries are growing rapidly, now up to over 2 million "entries" per year, posing an ever-increasing challenge to our ability to ensure that those foods are safe and wholesome. In fact, we can only inspect under 10 percent of food imports and, of those inspected, thousands must be "detained" as being in violation of our standards.
- o The cumulative effect of years of exposure to pesticides and other chemical contaminants is uncertain, but public concern about those food contaminants has remained high for a generation.
- o Hardly a month goes by in which there is not a public scare over the latest contaminant in food -- Alar in apples, aldicarb in watermelon, EDBC in flour, PCBs in fish, lead in ceramicware, cholera in shellfish, dioxin in food packaging, salmonella in eggs, *Listeria* in cheese, and more (many of which are not true health problems, but are perceived as such by the public). The *E. coli* incident in Washington state is only the latest in a long series.
- o There are enormous inefficiencies in the current food protection system. For one example, FDA, USDA, and state agencies duplicate efforts in some areas. For another, FDA wastes resources attacking problems with antiquated enforcement authority (for example, having to go to a U.S. Attorney to seek judicial seizure of a contaminated food when most agencies could merely detain it administratively).
- o Although our principal concern should be public health, you should know that the United States has an annual export surplus of \$8 billion, and foreign buyers are increasingly asking for government "certification" that U.S. foodstuffs are safe.

Page 5 -- The Secretary

WHAT IS NEEDED TO SOLVE THE PROBLEM

Years of experience with foodborne public health threats and with regulation of the food supply, as well as numerous public and private reports on food safety, have suggested that there are additional steps that may be appropriate to adequately ensure the safety of our Nation's food supply, including:

- 1) A Uniform National System of Food Safety Assurance - We need to design a system under which the food industry subscribes to a comprehensive food safety assurance program to improve both efficiency and effectiveness, which would govern the handling, processing, transportation, and preparation of food, and that would focus on the areas where we know food is most likely to become contaminated or otherwise threatened (e.g., adequate refrigeration in holding and shipment; adequate protection from chemical contaminants, pests, and pathogens; and adequate handling and cooking during processing). If implemented, this should comprise a coordinated regulatory framework encompassing the states, HHS, USDA, and other agencies concerned about food safety.
- 2) Authority to Protect the Public - FDA lacks many of the modern enforcement tools available to virtually all other Federal regulatory agencies. For example, the agency is not authorized to detain a contaminated product, cannot require food firms to register, lacks explicit authority to inspect the records of a food processor, and cannot order a recall of a product known to pose a health threat.
- 3) Inspection and Sampling - While the food industry has grown enormously in recent years, and imported foods have increased substantially, FDA's inspectional resources have been reduced. We do not have the resources to inspect many food processing facilities regularly (on average, every eight years), and inspect only a tiny fraction of imported foods. In addition, FDA has lacked the resources to take a proactive role in the growing internationalization of food commerce, to ensure that food imports are safer at the source.
- 4) Other Needs - There is great need for additional research into the nature and biological action of pathogens, for better analytical methods to test for the presence of chemical and biological contaminants, and for more training for the state, local, and Federal inspectors who are charged with identifying such threats.

Page 6 -- The Secretary

THE FOOD SAFETY INITIATIVE

Despite the years of public disagreement about how to resolve the food safety problems, I believe that the basis for a new program exists that can have an enormously beneficial impact on health with little or no additional taxpayer funding. The program would involve three principal elements to strengthen FDA's role in improving food safety. These elements can be summarized as follows:

Regulations to Ensure Quality Control

We should promulgate new regulations that would require food producers, processors, transporters and retailers to prepare plans for controlling hazards within their operations. These regulations would be based on the proven concept of "HACCP"--Hazard Analysis Critical Control Points--which focuses on critical points in food processing that might permit food to become contaminated. The regulations could be tailored to each segment of industry, yet be national in scope to ensure consistent, uniform protection of the food supply. We believe we can build strong industry support for a broad HACCP program. In fact, we are working now with the National Fisheries Institute (the seafood industry trade association) on a mandatory HACCP program for seafood processors that will greatly improve seafood safety.

New Statutory Authority to Control Food Hazards

We should seek new authorities to ensure safe food handling and preparation, for example:

- to require food producers and handlers to register their facilities, so that we know where food is being produced and held, and by whom;
- to authorize FDA to require that all food producers, transporters, and retailers establish and maintain a comprehensive program to ensure the safety of the foods they handle--thus enabling FDA to positively certify their products for domestic and international commerce;
- to authorize FDA to refuse entry to food imports where the food safety inspection system of the originating country is not equivalent to the U.S. system and the food handler has not registered with FDA, does not have a HACCP program, or has refused FDA access to inspect the manufacturing facility;
- to permit an inspector to review a food producer's processing records;

Page 7 -- The Secretary

- to authorize FDA inspectors to detain a suspect food until its safety can be determined;
- to allow FDA to order the recall of a food found to be hazardous to health;
- to give FDA the flexibility to seek punishment for offenders short of criminal action, that is, to impose civil penalties as an intermediate deterrent; and
- to authorize the collection of user fees for some of FDA's food safety efforts, as described below.

Increased Resources to Protect the Food Supply

The level of effort to protect the food supply has simply not kept pace with the increasing size and complexity of the food industry and food imports. Indeed, as one comparison, USDA has 9000 employees devoted to the inspection of meat and poultry, while FDA has 770 for the entire rest of the food supply. We need to increase domestic inspections, import coverage, overseas inspections and standard setting, and other related activities such as HACCP development, research, and methods development. We are now examining those needs in detail so as to arrive at estimates of their likely costs.

HOW CAN FOOD SAFETY IMPROVEMENTS BE FUNDED?

I am keenly aware of the limitations on new funding for any Federal program. However, I believe we can develop a strategy that accomplishes our goals without seeking new appropriations.

First, there are areas of food protection that are appropriate for user fees. Last year the drug industry agreed to support user fees for increased FDA resources for drug reviews. That program promises to significantly reduce the time it takes to get new therapies on the market. In the food safety area, there are three sources of user fees that I recommend we consider--import examination, export certification, and establishment registration. Imposing an import fee merely requires that foreign importers pay for FDA to ensure that their foods are of sufficient quality to enter the United States. Export certification is a service provided to American exporters that provides a significant benefit to those exporters, by certifying to foreign governments that an American food export would be of acceptable quality in this country. Establishment registration fees would support the costs of registering a food processing facility with the FDA. We believe all of these fees can be designed to generate sufficient funds without creating an undue burden on food production or international trade.

Page 8 -- The Secretary

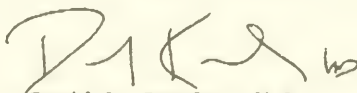
In addition to funding, we may be able to greatly enhance the use of existing resources with more modern inspection and enforcement powers. Also, the states have food safety programs, and it should be possible to design programs in which Federal and state officials ensure against duplication of effort while also improving coverage of the food supply.

Finally, USDA has substantial numbers of employees nationwide involved in all aspects of food production and marketing--not only meat inspection, but also insect control, land management on farms, grading of agricultural products, and other agriculture related activities. I recommend that we approach Secretary Espy about factoring joint HHS-USDA food safety protections into his comprehensive review of USDA's organization and mission, and that we explore ways of better coordinating HHS' and USDA's food safety activities. Indeed, Mr. Espy has said that meat and poultry safety--using the HACCP principles we are recommending--is high on his list of priorities. The Centers for Disease Control should be a part of any such discussions, as their role in epidemiological surveillance and disease prevention is an important part of protecting the public from unsafe foods.

RECOMMENDATION

I believe that food safety reform is essential to carrying out FDA's mission of protecting the food supply and the public health. It will have the ancillary benefits of strengthening the integrity (and thus competitiveness) of American agricultural exports and of lowering health care costs. Accordingly, I recommend that you announce, in consultation with Secretary Espy, that the Administration will initiate a comprehensive overhaul of the food safety assurance program--a program that will include new regulations requiring quality assurance programs based on the HACCP concept, new legislation to strengthen FDA's enforcement authorities, and statutory authority to assess user fees to fund the new food safety program.

Dr. Lee and I are available to discuss these recommendations with you at your convenience.



David A. Kessler, M.D.
Commissioner of Food and Drugs

DECISION

Announce and implement a new food safety initiative as proposed.

Concur _____ Nonconcur _____ Date _____

May 20, 1993

NOTE TO DR. LEE

Phil,

The attached note relates to the recent meeting with FDA and CDC staff on our proposal for a food safety initiative. Kevin promised to get back to us within a couple of weeks. But I wanted to react to some of his concerns, thus this note. Principally, he was concerned that FDA had enough on its plate already and should be careful about launching major new initiatives, and that it would be difficult to find funding for a significant new program. My reaction is that the initiative should be undertaken with whatever resources we can muster, because it is a priority, in my view, if FDA is to properly protect the food supply.

I understand that Kevin plans to discuss this in a senior staff meeting tomorrow.

A handwritten signature in dark ink, appearing to read 'D. Kessler', with a stylized flourish at the end.

David A. Kessler, M.D.

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

May 20, 1993

NOTE TO KEVIN THURM

Subject: Food Safety

I apologize for missing the recent meeting on food safety. Mike Taylor briefed me afterwards, and I wanted to follow up on some of the issues discussed.

First, I strongly believe food safety should be one of FDA's highest priorities in the coming years. It is a significant public confidence and public health issue and relates to preventing disease and controlling health care costs (as billions of dollars are now spent on treating foodborne illnesses that are mostly preventable). For these reasons, despite severe budget restraints, FDA will be requesting resource increases for food safety for FY '95.

By publicly endorsing food safety and HACCP as important HHS/FDA initiatives, the Secretary can provide leadership that will have immediate impact, meet some important external demands, and greatly assist FDA in achieving its food safety goals -- without having to invest a substantial amount of her personal time.

As you know, at the program's heart is the concept of having food manufacturers develop quality control systems (the "HACCP" concept), which enable them to demonstrate that food is handled, processed, and transported safely -- rather than forcing us to expend ever greater resources trying to chase down problems after they occur. This approach extends to the imported food area as well, where we've seen tremendous growth in imported "finished" products from less developed countries. These imports pose risks to U.S. consumers that we have great difficulty addressing under an inspection system that physically examines only a tiny percent of imported food shipments. Many of the more sophisticated U.S. companies already operate under HACCP principles, and the international community is moving swiftly toward HACCP. In a very real sense, the future of food safety is HACCP, whether we lead the effort or not.

We've had preliminary discussions about our ideas with USDA, industry and state officials, who are enthusiastic about its potential. Industry is obviously wary of user fees and new FDA enforcement authorities. But everyone recognizes that HACCP is a concept whose "time has come" and that implementing such a

Page 2 - Note to Kevin Thurm

program is in everyone's interest. Secretary Espy is committed to making fundamental reforms in the inspection of meat and poultry -- using the HACCP concept -- and the Vice President's task force on reinventing government considers that subject a high priority.

Finally, I understand that you and Ken Apfel had concerns about the budgetary effects of the initiative we outlined to you. It's a valid question that we're concerned about as well. The key point is that the HACCP concept itself is not the budget issue; it is the way FDA and the industry must do food safety if we are to be efficient and in step with the international state of the art.

Food safety is a budget issue. We are underfunded in relation to the growing demands being placed on the food safety system, which is why we have requested increases for seafood HACCP and other programs and will continue to seek ways to increase resources, including user fees where appropriate and politically feasible. But budget problems must not stop us from leading the transition to HACCP, which over time will enable us to make the most efficient and effective use of whatever food safety resources we have. We are not seeking any additional resources for the FY '93-'94 start up activities, which we believe constitute the best possible use of our current food safety resources.

As a next step, I recommend that FDA officials engage USDA more formally in discussing a joint initiative, with the goal of Secretaries Shalala and Espy announcing their plans to lead a reform of food safety regulation.



David A. Kessler, M.D.

Commissioner of Food and Drugs

cc: Claudia Cooley
Phil Lee

Strategic Alliances . . . Foods Jurisdiction

THE FOODS PROGRAM IS PARTICULARLY CHALLENGING GIVEN THE NUMBER OF FEDERAL AGENCIES INVOLVED IN FOODS

Commodity Category	Develops Product Standards, Grades, or Certification Criteria, or Labeling or Advertising Regulations				Performs Inspections and Lab Analyses (testing) for Enforcement**					
	Safety or Sanitation FSIS, EPA FDA	Economic Promotion AMS	Economic Deception FDA—eggs FSIS FDA	Product Labeling FSIS FDA	Product Advertising FTC, AMS	Safety or Sanitation FSIS, AMS, FDA APHIS, CDC FDA	Economic Promotion AMS NMFS, APHIS	Economic Deception FSIS, AMS FDA	Product Labeling FSIS	Product Advertising FTC
Meats and Eggs	FDA	AMS	FDA	FSIS	FTC, AMS	FSIS, AMS, FDA APHIS, CDC FDA	NMFS, APHIS	FDA	FDA	FTC
Non-domesticated Seafood	NMFS, FDA EPA	NMFS, APHIS	NMFS, FDA	NMFS, FDA	FTC	NMFS, FDA	NMFS, APHIS	NMFS, FDA	FDA	FTC
Dairy	EPA, FDA	AMS	FDA	FDA	FTC	FDA, CDC AMS	AMS	FDA, AMS	FDA	FTC
Grain, Cereal, Milling, Bakery	FDA, EPA	FGIS	FDA, FGIS	FDA	FTC	FGIS, FDA APHIS	FGIS	FGIS, FDA	FDA	FTC
Sugar, Confectionery	EPA(?) FDA	AMS—nuts	FDA	FDA	FTC	FDA, AMS		FDA, AMS	FDA	FTC
Edible Oils	EPA FDA		FGIS(?) FDA	FDA	FTC	FDA, APHIS NMFS—fish		FDA NMFS—fish	FDA	FTC
Fruit, Vegetables, Sauce, Dressings	EPA FDA	AMS	FDA	FDA	FTC	FDA, AMS APHIS	AMS	FDA, AMS	FDA	FTC
Alcoholic Beverages	ATF, EPA(?) FGIS(?)		ATF	ATF	ATF, FTC	ATF		ATF	ATF	FTC
<7% Alcohol	FDA		FDA	FDA	FTC	FDA		FDA	FDA	
Sodas, Flavorings	FDA		FDA	FDA	FTC	FDA		FDA	FDA	
Bottled Water	FDA		FDA	FDA	FTC	FDA		FDA	FDA	
Animal Feed	FDA, EPA FSIS	AMS	FDA	FDA	FTC	FDA, AMS APHIS	FSIS	FDA FSIS(?) FDA	FDA FDA	FTC FTC
Vitamin and Nutrient Supplements	FDA		FDA	FDA	FTC	FDA		FDA	FDA	FTC
Housewares	FDA		FDA	FDA	FTC	FDA		FDA	FDA	FTC
Miscellaneous Food Products	EPA, FDA	AMS	FDA	FDA	FTC	FDA, CDC APHIS		FDA	FDA	FTC

Sources: (1) Food Safety and Quality: Who Does What in the Federal Government, GAO, Dec. 1990. (2) Personal communications.

* Many inspection and enforcement activities are performed by state officials in cooperation with Federal rules, e.g., EPA pesticide inspections, FDA dairy plant inspections, FSIS state plant sanitation inspection programs.

** The U.S. Customs Service works with FDA to secure the final disposition of violative imported food products.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service


Office of the Assistant Secretary
for Health
Washington DC 20201

AUG -6 1993

TO: Commissioner of Food and Drugs
FROM: Assistant Secretary for Health
SUBJECT: Consideration of FDA Initiatives

This follows our phone conversation last Thursday, July 29, regarding your memo, jointly signed with Dr. Cross, to Secretaries Espy and Shalala. I appreciate your consideration of my concerns, both about your memo on food safety cooperation and about your preparing and signing material directly to the Secretary. I am returning your July 28 memo following consultation with the Chief of Staff and the Secretary about its appropriateness and timing. Also, regarding FDA's ongoing preparation of decision and information material on the broad spectrum of critical issues, I ask that you consult with me in advance, present work through channels to me, and prepare material for the Secretary either from me or through me.

I appreciate the enormously important mission of the FDA, the high level of expertise resident there, and the extreme pressure of mandated time for regulatory activity to improve public health. I have talked about this matter with my own staff and staff in the Office of the Secretary, and we are determined to be supportive of FDA initiatives within the framework of Administration policy and guidance. Please bring such issues to my attention so that I might be maximally responsive and responsible as the Assistant Secretary for Health.


Philip R. Lee, M.D.

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUL 28 1993

Memorandum

To: SECRETARY OF AGRICULTURE
SECRETARY OF HEALTH AND HUMAN SERVICES

Subject: Food Safety Cooperation

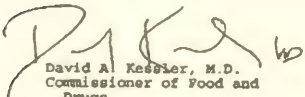
As you know, recent incidents of foodborne illness have raised public concerns about the safety of the nation's food. Our respective departments have been considering how we can improve our food inspection programs to better assure that food marketed in the United States is safe and wholesome and to raise public confidence in our regulatory system.

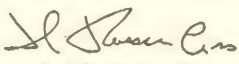
We have each determined that a major key to improving food inspection and bolstering public confidence in the food supply is to require that food producers establish systems of preventive controls, known as "HACCP" (Hazard Analysis and Critical Control Points). Under HACCP, companies are responsible for producing their food products using an effective system of food safety controls. The government inspectors verify that the systems food producers have in place are adequately designed and functioning effectively, and they use the information produced by the systems to obtain a larger picture of the plant's operations than they can obtain under the current system of inspection.

The HACCP concept is already being widely adopted internationally and has become the "state of the art" technique for controlling foodborne hazards. Adopting it here will not only provide greater assurance of safety, it will make our products more competitive internationally and make more efficient use of our scarce food regulatory resources.

Both our agencies have been working on proposed regulations that would institute HACCP controls in the food industry over time. FDA's first step, a seafood rule, is in final HHS review; the FSIS rule for all meat and poultry will be completed in August. Our proposals are substantively consistent, and together, they represent a major advance in food safety. They also demonstrate that the Clinton Administration is working effectively to address an important public health issue.

The FDA and FSIS staff have been discussing the details of our plans over the past few weeks, and we are planning to jointly brief OMB no later than mid-August. In anticipation of OMB approval soon thereafter, we would like to propose that you convene a press conference as soon after Labor Day as possible to jointly announce publication of the new regulations as a major Administration initiative and an example of how USDA and HHS will be working together in the food safety arena. We expect that such an announcement will be well received by both consumer groups and the food industry.


David A. Kessler, M.D.
Commissioner of Food and
Drugs


H. Russell Cross, Ph.D.
Administrator, Food Safety
and Inspection Service, USDA

I-2814



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

AUG 13 1993

MEMORANDUM TO THE EXECUTIVE SECRETARIAT

Attn: Joni Cunningham

FROM: Kenneth S. Apfel *KS Apfel*
Assistant Secretary for Management and Budget

SUBJECT: Proposed FDA Seafood Safety Regulation

We have reviewed the memorandum from Dr. Kessler of August 13 as to how FDA can implement the seafood safety regulation within existing resources. While we still believe there is a need to develop better resource estimates for the out-years, we concur on forwarding the proposed regulation to OMB.

Attachment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 13, 1993

MEMORANDUM TO KENNETH APPEL

FROM: Commissioner of Food and Drugs

SUBJECT: Resources to Implement FDA's Seafood Regulation

As I discussed with you yesterday, we have been planning for implementation of the seafood regulation based on various funding scenarios. This memorandum is intended to confirm our conversation, in which I detailed how we can put the regulation in place with existing resources (i.e., in the absence of additional resources to maintain or increase our current level of inspection).

There are many activities that must be accomplished over the next few years as the regulation comes into effect. Two of those activities--inspection of seafood processors and training of FDA inspectors to conduct HACCP inspections--must be carried out by FDA employees. As I told you on the telephone, we currently expend about 40 FTEs directly for domestic seafood inspections, which take on average about 22 hours to perform. That level of effort permits us to inspect high risk seafood firms about once a year and lower risk firms once every 3.5 years.

Under the new HACCP regulations, there will be a start-up period during which we will be transitioning to a different kind of inspection, and those initial inspections will take longer than our current inspections. Thus, without additional inspection resources, we would stretch out our inspection schedule by inspecting each plant less frequently, but still focusing the most attention on the highest risk firms. This is acceptable because the implementation of HACCP will greatly improve the ability of seafood processors to reduce health risks, and our inspections will give us a much more meaningful view of each processor's ability to ensure quality control. As we get HACCP implemented over the first 3 years, we believe inspections will drop closer in length to current inspections, enabling us to return to the same inspection intervals that we now have.

We must recognize, however, that FDA has been under great criticism from Congress and consumer groups about our inspection intervals for seafood and for all other foods. Whether we carry out inspections as we currently do, or transition to a HACCP-based inspection system, the need for resources to increase our inspectional coverage will remain an issue. Thus, irrespective of HACCP, we will continue to seek ways for increasing the resources for food safety.

The other mandatory activity for FDA's transition to HACCP is training FDA inspectors in HACCP principles. However, we have already begun such training and believe that the three year interval between now and the time HACCP inspections are likely to begin gives us sufficient time to phase that training in within our existing training budget.

Other activities that must be conducted to implement HACCP include hazard analysis, training of manufacturer employees, and standard setting. We believe there are substantial opportunities to have the burden of those efforts carried by the private sector or shared with us in cooperative arrangements.

I hope this answers your questions about this important regulation. I will be available for further discussion if necessary.



David A. Kessler, M.D.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

AUG - 2 1993

MEMORANDUM TO THE EXECUTIVE SECRETARIAT

Attn: Joni Cunningham

FROM: Kenneth S. Apfel *KS*
Assistant Secretary for Management and Budget

SUBJECT: Proposed Rule Establishing Procedures for the Safe
Processing and Importing of Seafood

We have reviewed the draft proposed rule which would establish procedures for regulating seafood along the Hazard Analysis Critical Control Point (HACCP) principles. While on a conceptual basis HACCP appears to be a well thought out regulatory approach, we are concerned about the lack of information and analysis concerning the cost to FDA of implementing HACCP. Prior to concurring with this regulation, we would like the opportunity to review the resource requirements (dollar and full-time-equivalent) necessary for FDA to implement this regulation over the next 5 years. In addressing this question, we would like the FDA to identify or project the number of inspections anticipated each year over the next three years, comparing this to the inspection levels over the past three years. The response should also include a discussion of the extent and source of required reallocation necessary to finance this initiative in FY 1994 and FY 1995.

In addition, it is our understanding that the National Performance Review is considering recommending a HACCP approach for regulating foods and requiring user fees be collected to cover the costs of reviewing the HACCP plans. In view of this specific proposal, FDA should also discuss the merits of funding this HACCP proposal through user fees.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

SEP 2 1993

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Assistant Secretary for Health

SUBJECT: FDA Food Safety Initiatives and Proposed Rule for Seafood HACCP; Friday,
September 3, 1993 at 2:15 p.m.--BRIEFING

PARTICIPANTSHHS Officials

Walter Broadnax, Deputy Secretary
Kevin Thurm, COS
Joni Cunningham, OS Executive Secretariat
Harriet Rabb, GC
Avis LaVelle, ASPA
Ken Apfel, ASMB
David Ellwood, ASPE
Jerry Klepner, ASL
Philip Lee, ASH

FDA Officials

David A. Kessler, Commissioner
Michael Taylor, Deputy Commissioner for Policy
Mitch Zeller, Special Assistant for Policy

BACKGROUND

FDA is the lead food safety agency within the Federal government, largely through its enforcement of the food safety provisions of the Food, Drug, and Cosmetic Act of 1938. The Act's food safety provisions have remained essentially unchanged, but the food supply has changed dramatically between the time of the Act's passage and today. Accompanying changes in food processing and consumption has been a rise in food borne illnesses, caused by many factors (e.g., new pathogens, changes in food handling, increased transport of food over long distances, environmental pollution). FDA has identified an urgent need for a new comprehensive Federal policy for food safety, in keeping with proven concepts of Hazard

Page 2 - The Secretary

Analysis Critical Control Point (HACCP) principles. A HACCP system involves preventive controls to keep hazards from occurring. It is the most effective and efficient way to ensure that these products are produced under preventive controls that ensure safety by design. HACCP has been endorsed by the international Committee on Food Hygiene of the Codex Alimentarius Commission, and food safety groups (e.g., National Academy on Microbiological Criteria for Foods, and the National Academy of Sciences).

ISSUES OF CONCERN

There is broad support in the food industry and in Congress for moving forward with HACCP as the basis for producing safe food and making the best use of FDA's and USDA's inspectional resources. USDA is moving its own HACCP for meat and poultry, and prompt action on FDA's seafood rule is necessary so that FDA can maintain its leadership role and the Administration's food safety efforts can be coordinated.

Additionally, with respect to seafood, the European Community (E.C.) has already begun to demand certification of seafood, and is phasing in a requirement that seafood be processed under HACCP plans. If HACCP for this industry is not implemented, U.S. manufacturers may be unable to ship their seafood to the E.C., and would lose a multi-million dollar market.

DISCUSSION

FDA is prepared to develop new regulations that would require the food industry to prepare plans for controlling hazards within its operations. The regulations would be based on the proven concept of HACCP, which focuses oversight on critical points in food handling that might permit food to become unsafe. The rules would be national in scope to ensure consistent, uniform protection of the food supply.

Under the current regulatory system, FDA's inspection and surveillance strategy verifies the industry's knowledge of hazards and preventive control measures largely by inference, *i.e.*, whether a company's products are adulterated as determined by FDA sampling and analysis, or whether conditions in a plant during inspection are consistent with good manufacturing practice. Consequently, the burden is on FDA to prove that a problem exists, rather than on a firm to establish for itself, for the regulator, and for consumers, that it understands the hazards and has adequate controls in place to ensure safety. The system places a significant burden on the government to uncover problems, without fostering or promoting industry responsibility. It lacks preventive controls that ensure safety by design.

If the HACCP system is adopted, FDA will monitor the adequacy of HACCP controls as part of its program of mandatory inspections and import examinations. This review will be more comprehensive than the review provided for by current inspections. FDA will be able to impose sanctions if a firm's preventive controls are inadequate.

Page 3 - The Secretary

A key feature of the HACCP system is recordkeeping. A firm operating under HACCP must monitor its preventive controls, document the results, and make those monitoring records available to inspectors. FDA currently does not have mandatory access to a firm's safety monitoring records. Through these records, inspectors can view the critical functions of the operation since the last inspection. They can determine whether the firm is practicing safety by design. They can spot trends that could lead to safety problems in the future if not corrected and can determine how well the firm has responded to problems.

Seafood's place in FDA's food safety program plans - FDA has chosen seafood for its first HACCP proposal. Consumers, Congress and others have been pursuing significant improvements in the regulation of seafood, as reflected by HACCP, since the 1980s. The application of HACCP to seafood is at an advanced stage of development, relative to other foods that FDA regulates.

Ensuring the safety of seafood presents special challenges to both the industry that produces it and to FDA. Unlike beef and poultry, seafood is still predominantly a wild caught flesh food that is exposed to a wide variety of environmental hazards before capture. It must be harvested under frequently difficult conditions and at varying distances -- often quite significant -- from processing, transport, and retail facilities. These conditions, distances, and duration of fishing trips can tax any system of controls designed to assure safety.

The seasonal nature of the industry can affect worker skills and practices relating to safety, while the older facilities and equipment that are used by much of the industry can be difficult to maintain in terms of adequate sanitation and proper processing and storage temperatures. It is of utmost importance, therefore, that those who handle and process seafood commercially, including importers, understand the hazards associated with this type of food and keep these hazards from occurring through a system of preventive controls, routinely applied.

I have reviewed and approved the proposal for seafood and the document is now awaiting your review and approval (See Decision Memorandum at Tab A). Some revisions have already been implemented in response to concerns raised by ASPE, and FDA is revising and completing its economic evaluation. We look forward to discussing the proposal with you in more detail at the briefing.



Philip R. Lee, M.D.

Attachment

Tab A - Decision Memorandum: Seafood Proposed Rule

Page 4 - The Secretary

docname:seafdb2.aac

drafted: AChamblee:HF-40:8/31/93

revised: ABach:HF-40:9/1/93

reviewed/cleared: by JRiggins September 1, 1993

MTaylor: September 1, 1993

FShank/EElliott: September 1, 1993



DEPARTMENT OF HEALTH & HUMAN SERVICES

FD-204 (Rev. 10-1-80)

July 3, 1993

Food and Drug Administration
Rockville MD 20857MEMORANDUM

TO: The Secretary

 Through: DS _____
 COS _____
 ES _____
 Acting ASH _____
 AGC *MA [signature]* _____

FROM: Commissioner of Food and Drugs

SUBJECT: Proposed Rule Establishing Procedures for the Safe Processing and Importing of Seafood - DECISION

BACKGROUND

I am submitting for your approval proposed regulations, attached, to establish procedures for the safe processing and importing of fish and fishery products in keeping with Hazard Analysis Critical Control Point (HACCP) principles. A HACCP system involves preventive controls to keep hazards from occurring. It is the most effective and efficient way to ensure that these products are safe.

HACCP was first applied to food safety by the Pillsbury Company in the early 1960's to develop a safe food for astronauts. Since then, it has been recognized and adapted throughout the developed world. The European Community and major seafood exporting nations such as Canada, Australia, Iceland, and New Zealand are moving toward, or already have, HACCP systems in place for seafood.

THE CHALLENGE OF SEAFOOD

Ensuring the safety of seafood presents special challenges to both the industry that produces it and to FDA. Seafood encompasses over 350 edible species from a wide range of habitats. These habitats all have a bearing on the types of microorganisms, toxins, parasites, chemicals, and other potential hazards to which fish are exposed that can affect human food safety. Over 55% of seafood consumed in the U.S. is imported from 135 countries.

Unlike beef and poultry, seafood is still predominately a wild-caught flesh food that must be harvested under frequently difficult conditions and at varying distances -- often quite significant -- from processing, transport, and retail facilities.

9303310

The Secretary -- Page 2

These conditions, distances, and duration of fishing trips can tax any system of controls designed to assure safety and prevent spoilage. In addition, several hundred vessels are seagoing processing factories, many of which operate in remote waters.

The seasonal nature of the industry can affect worker skills and practices relating to safety, while the older facilities and equipment that are used by much of the industry can be difficult to maintain in terms of adequate sanitation and proper processing and storage temperatures.

Although the National Academy of Sciences concluded in 1991 that commercial seafood is generally safe, illnesses do occur. It is of utmost importance, therefore, that those who handle and process seafood commercially, including importers, understand the hazards associated with this type of food, know which hazards are associated with the types of products with which they are involved, and keep these hazards from occurring through a system of preventive controls, routinely applied.

ADEQUACY OF THE CURRENT REGULATORY SYSTEM

The current regulatory system, which was developed for the general food supply, is not well suited for the seafood industry. FDA's current inspection and surveillance strategy verifies the industry's knowledge of hazards and preventive control measures largely by inference, i.e., whether a company's products are adulterated as determined by FDA sampling and analysis, or whether conditions in a plant during inspection are consistent with good manufacturing practice. Consequently, the burden is now on the agency to prove that a problem exists, rather than on a firm to establish for itself, for the regulator, and for consumers, that it understands the hazards and has adequate controls in place to ensure safety.

An FDA survey of certain high risk seafood processing operations reveals that the industry does not always operate on the basis of preventive controls. For example, significant percentages of firms surveyed did not know whether their pasteurization processes were adequate to destroy pathogens; did not monitor internal product temperature; did not have accurate thermometers; and did not know the results of their own sanitation efforts. This survey is described in greater detail in the preamble to the proposed regulation.

Moreover, the current system of intermittent inspection provides FDA with only a "snapshot" of conditions at a facility at the moment of the inspection. The agency must make assumptions about conditions before and after that inspection on the basis of the "snapshot", as well as about important factors beyond the facility that have a bearing on the safety of the finished product. The reliability of these assumptions over the intervals

. The Secretary -- Page 3

between inspections creates questions about the adequacy of the system, as demonstrated by the 11 congressional hearings on seafood safety since 1969.

Similar considerations apply to imports. FDA can physically examine less than 5 percent of seafood lots offered for entry into this country. The resources that would be needed for FDA to physically examine a statistically significant number of lots would be staggering. While many importers are conscientious about the safety and quality of the products that they import, others have little understanding of potential hazards. The system places a significant burden on the government to uncover problems without fostering or promoting industry responsibility. It lacks preventive controls that ensure safety by design.

THE HACCP SYSTEM

Our new regulation would require that seafood processors and importers put in place a structured program of preventive controls (i.e., HACCP) to ensure the safety of seafood sold commercially in the United States and exported abroad.

If the proposal is adopted, FDA will review the adequacy of HACCP controls as part of its program of mandatory inspections and import examinations. This review will be in addition to, not as a replacement for, comprehensive inspections. FDA will be able to impose sanctions if the firm's preventive controls are inadequate.

A key feature of the HACCP system is recordkeeping. A firm operating under HACCP must monitor its preventive controls and document the results. A firm that is subject to a HACCP-based inspection by FDA must make those monitoring records available to inspectors. Through these records, inspectors can view the critical functions of the operation since the last inspection. They can determine whether the firm is practicing safety by design. They can spot trends that could lead to safety problems in the future if not corrected and can determine how well the firm has responded to problems. All foreign processors that export to the U.S. will be required to operate under HACCP systems. Importers will be required to possess HACCP plans from their foreign suppliers.

ECONOMIC IMPLICATIONS

Although we lack the data at this time to conduct a definitive economic assessment of the costs of this rule, our assessment at this time is that the regulation will cost no more than \$82 million the first year and \$60 million in succeeding years. Our preliminary benefit assessment has estimated that benefits of the rule will greatly exceed costs.

1 The Secretary -- Page 4

OPTIONS NOT SELECTED

Options not selected were: (1) continuation of the current approach at present funding levels; (2) continuation of the current approach but at much higher funding levels that permit more frequent inspections and the taking of many more samples; (3) adopting the continuous, inspector-in-every-plant approach now operated for beef and poultry by The U.S. Department of Agriculture (USDA).

Continuing the current approach at today's funding levels suffers from the problems already discussed. Continuing the current approach but at much higher funding levels would represent an attempt to overcome the inefficiencies in the current system through spending. Theoretically, this could be done, but the drain on scarce public health resources would be significant. The option of continuous visual inspection would be even more expensive and would be highly misdirected as well, because most seafood hazards cannot be detected through continuous visual observation of fish on an assembly line. None of these approaches, moreover, requires that the seafood industry demonstrate that it understands the hazards and is controlling them as a matter of design.

By contrast, the HACCP option need not require the expenditure of significant additional public health resources. FDA can review a firm's HACCP control in the frequency of inspections. Actually, inspections as part of the current inspection regime without any increase of firms operating under HACCP may take the agency longer per inspection, at least in the short run, so the frequency of inspections might decrease slightly. However, the impact of each inspection will be significantly increased. This is the conclusion that the Canadians reached when they switched their regulatory program for seafood to HACCP.

CONSEQUENCES OF DISAPPROVAL

There are several consequences of disapproval. First, complete consumer confidence in seafood will never be achieved under the current system. It does not exist now and will likely erode further should beef and poultry be brought under a HACCP system - as USDA is currently working to do -- but seafood is not. Second, failure on our part to establish a HACCP program administratively would likely lead to renewed congressional action to enact seafood legislation to move the seafood program out of HHS.

EXPECTATIONS

The National Academy of Sciences advocated the application of HACCP to seafood processing in its 1991 report on seafood safety. Consumer groups have supported seafood legislation that would

The Secretary -- Page 5

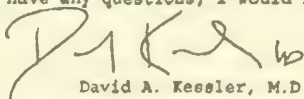
have authorized mandatory, HACCP-based inspection systems for seafood. Significant elements of the domestic seafood industry are urging the Federal government to institute a mandatory, HACCP-based inspection program.

URGENCY

The regulation of the food supply needs to be placed on a more rational footing. Immediate action on these regulations will enhance the Secretary's ability to assert leadership with regard to seafood safety and food safety generally. These regulations are intended to be the vanguard for a larger HHS food safety initiative, part of which will involve the application of HACCP controls to other foods.

RECOMMENDATION

I have signed the subject proposed rule. I recommend that you sign this proposal and approve its publication in the Federal Register. If you have any questions, I would be happy to meet with you.

A handwritten signature in dark ink, appearing to read 'D. A. Kessler', with a stylized flourish at the end.

David A. Kessler, M.D.

Attachment

SEP 1 - 1993

NOTE TO BOB RICKARD:

The COS has requested a big picture briefing on food safety before forwarding the seafood regulation to the Secretary for signature. Since the seafood regulation is very important to FDA, they have asked that we use to time for the pesticide briefing (Friday, 2:30) to include a seafood briefing. This suggestion has been well received, and we have added 15 minutes to the Friday time, so that the briefing will begin at 2:15.

Please advise FDA that they will brief the Secretary on food safety generally, highlighting the seafood regulation and FDA's activities with EPA and USDA on pesticide reduction in foods. Thank you.

Joni Cunningham, ES
690-7160

cc: Carol Wigglesworth



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date

Mar 22 1994

From

Acting Director, Office of Management Systems (HFS-650)

Subject

FY 96 Plan

To

Bob Navazio

Director, Planning and Management Communication Staff, (HFP-20)

Through: Director, Center for Food Safety

and Applied Nutrition (HFS-1)

Attached is the final draft of the Food and Cosmetics program FY1996 Plan. In this package you will find: a summary table of Base resources for FY96 planning, a summary of plans supporting each of the Agency strategic areas, and format page write-ups on pre-market review and CFSAN's priorities in food safety, science and labeling.

Our Planning Branch (HFS-666) has provided an early draft to your Program Information and Analysis Group (HFP-25) and will continue to work with them to edit minor changes. The resource estimates in the early draft have not been changed in the final draft.

If you have any questions or need more information on the FY96 Plan, please call Ellis Norris or Pete Salsbury in the Planning Branch at 202-205-4564.

James F. Trickett

Attachments

cc:

HFS-1

HFS-2

HFS-3

HFS-4

HFS-665

HFS-666

HFS-667

Food and Cosmetics Safety

Although the United States has the world's safest food supply, there are still needs and opportunities for improvement. Under each of the Agency's Strategic Goals listed below, there are discussions of specific areas where improvements are needed and the strategies that will be used to address those needs. Since FDA has the broadest responsibility of any federal agency for the regulation of foods, any improvements under this program which result in a safer, more sanitary, and more wholesome food supply will ultimately have a substantial impact on the health of the Nation and directly contribute to accomplishing goals set for the Healthy People 2000 initiative.

Pre-Market Review

Assuring the safety of food and color additives intended for use in foods, cosmetics, drugs, and devices is a major responsibility of the Food and Cosmetic program. At present approximately 70 FTE's per year are devoted to the review of food and color additive petitions. Despite this level of resource investment, the inventory of petitions awaiting action has increased by over 50% since FY 1984 and now stands at 319. Approximately 116 of these petitions are "overdue" -- there are no unaddressed outstanding questions and no substantive amendments have been received within the last 180 days.

The increase in the food additive petition inventory can be attributed largely to two factors. One is the lack of adequate resources to keep pace with this responsibility. For instance, there has been a 20% decline in the resources available for food additive petition review since FY 1978. Another important factor is that some of the newer petitions (e.g., those for artificial sweeteners and microparticulated products) have tended to take longer to review because they sometimes raise new and substantially more complex and controversial safety issues.

One of the Center's strategic goals for FY 96 is to continue efforts to significantly increase the number of petitions that are processed within the established statutory timeframes and decrease the total number of "overdue" petitions in the inventory. While the strategy to accomplish this will require additional resources, emphasis will also be placed on the implementation of several new initiatives that are designed to make the petition review process more efficient. One of these initiatives will focus on developing and implementing strategies to resolve food and color additive policy issues that affect the timely resolution of approval decisions. Another will focus on enhancing the quality of incoming petitions by improving guidelines for preparing petitions and communicating these to industry. Also, the Center will work to revise and streamline FDA's criteria for determining the GRAS status of food ingredients as well as to develop procedures and create systems for electronically accepting, transferring, and

provided through the current inspections and sample collections and analyses.

By FY 96, FDA will need to begin verifying the existence and effectiveness of HACCP systems in the seafood industry. Prior to undertaking this effort, the Agency will need to revise its inspection procedures to complement the HACCP program, including the review of HACCP plans, verification of their implementation, and review of HACCP-generated monitoring records. There will also be a need to assure that all seafood investigators have been trained in HACCP principles so that they are able to conduct inspection using the revised procedures. In addition, the Agency will need to continue to work with industry associations to advise firms of the requirements, to provide guidance and assistance establishments on HACCP system development, and work with states to coordinate the implementation of the regulation.

Another goal for FY 96 will be to expand the surveillance activities for food labeling in order to assure that the food industry is complying with the NLEA regulations. There will also be a need to continue the aggressive effort to encourage states to adopt the "Food Code". The Food Code is intended operate in tandem with the new HACCP regulations by providing a framework for states to apply HACCP principles at the retail level. It is specifically designed to assist food control jurisdictions at all levels of government by providing them with a scientifically sound and legal basis for more effectively regulating the retail segment of the food industry.

Foods Safety (Foods Coordination)

If FDA is to achieve optimum effectiveness in efforts to regulate the Nation's food supply, its activities must be properly coordinated with those of other governmental and non-governmental entities which share responsibility for the safety of foods. These relationships benefit the Agency's regulatory efforts in several ways. They provide opportunities for FDA to increase its surveillance coverage of foods and cosmetics, expand its research activities, gain access to needed research facilities, as well as provide increased access to safety, surveillance, and food consumption data.

For FY 96, one important objective will be to continue efforts to improve collaboration and coordination with the States to promote consistency of interpretation among the States and FDA in the food safety program. This will include a continuation of efforts to promote the adoption by States of the "The Food Code" as the most effective and efficient means of ensuring food safety at the retail level.

Another objective will be to promote the formation and support of interagency working groups and committees (e.g., those currently involved in Microbiological Hazards, Chemical Contaminants, National Nutrition Monitoring, and Healthy People 2000) to deal

with regulatory issues, data gathering efforts, and emerging problems. For instance, efforts will be made to resolve differences in risk assessment procedures in use among Federal agencies (e.g., EPA, OSHA). Also, in cooperation with other PHS agencies, EPA, NOAA, USDA, State agencies, and academic institutions, CFSAN will work to develop and implement a coordinated research and information gathering network to support food safety policies and guidance. In addition, CFSAN will continue its joint efforts with CDC and USDA to determine the true incidence of foodborne microbial disease in the U.S. in order to measure progress towards achieving the Healthy People 2000 goal for reducing foodborne illnesses.

International Harmonization

In the international arena, one of the Center's important objectives is to develop and implement procedures for increasing the harmonization between this Nation's food regulations and those of other national governments. In recent years representatives of FDA have been involved in a number of international efforts (including the General Agreement on Tariffs and Trade [GATT] and the North American Free Trade Agreement) to harmonize standards, regulations, and technical competence related to foods. Full participation in such efforts are essential if FDA is to assure that standards which are set for foods through international negotiations provide the highest level of safety and sanitation protection for the American consumer. Another aspect of this objective is to make certain that these standards provide a "level playing field" for the U.S. food industry in international trade.

CFSAN has established several specific objectives for its international harmonization activities in FY 96. One is to continue to work with other nations to establish procedures for insuring the harmonization of food and color additive data requirements and regulations. This will include efforts to harmonize the flavor regulations with those of the European Union (EU) in keeping with the Joint agreement reached during the Fourth Bilateral Meeting (October 1992). In addition, efforts will be made to increase the Agency's participation in deliberations of the Codex Alimentarius Commission (CAC), its Committees, and associated organizations (such as ISO, IDF, AOAC) on activities to improve international harmonization on food additives, food hygiene, and foodborne contaminants. The development and implementation of HACCP programs will be another important issue considered during the deliberations of these organizations.

The Center will also continue to promote MOUs and mutual recognition agreements on foods with foreign countries. These agreements will help improve the Agency's ability to protect consumers and achieve objectives for international harmonization while conserving its scarce surveillance resources.

Science Base

In order to effectively respond to the new and traditional health hazards associated with foods and cosmetics, FDA must continually work to improve the scientific base upon which its regulatory decisions are made. Despite investing approximately 17% (approximately 449 FTEs) of the Food and Cosmetics program's resources in research activities, the Center has not been able to develop and retain all the critical scientific expertise required to respond to some of the emerging food and cosmetic related health issues. In addition, staffing limitations, pay limitations, and inadequate research equipment and facilities are among factors which have severely hampered the Center's ability to attract people who have the types of expertise required to help the Agency stay at the cutting edge of food science research and food safety policy development.

Currently CFSAN needs to improve its science base to support effective regulatory initiatives in several important areas. For instance, provisions of the North American Free Trade Agreement (NAFTA) require that regulatory decisions related to the safety of food be made on sound scientific principles. There is also a need to enhance the science base to support expanded regulatory programs for special nutritionals, including food supplements and medical foods. Another critical need is to have the information and expertise required to better understand and evaluate the safety of biotechnology products and biotechnology processing systems. Specific needs in this area include information on the formation and fate of biochemical and other byproducts which develop during processing and the development of biosensors which can be used to monitor safety factors and detect bacterial and chemical contaminants during processing. Important science base needs in other areas include additional specialized expertise in food composition research, food engineering experience with new food processing and packaging systems, and research experience related to innovative production techniques.

For FY 96, CFSAN will request additional resources to help fill developing gaps in the science base for foods and cosmetics. However, since it appears that the budget appropriations process will not provided all the additional resources that are needed, the Center will attempt to enhance its science base through several other means. For instance, it will place even greater emphasis on achieving better coordination with other FDA centers related to the planning and conduct of research projects on food safety as well as the sharing and use of research results from these projects. In conjunction with several other Centers (including NCTR, ORA, CDER, and CVM), CFSAN has established the Foods Research Governance Group. This group of Center Directors will review the research programs of each participating Center and work to identify areas of potential coordination and to eliminate any duplications of efforts. Internally the Center will perform more critical reviews of its research to assure that it is clearly mission relevant. These efforts will help assure that FDA's total foods research

program is properly focused and clearly supports activities to more effectively regulate foods.

CFSAN will attempt to more effectively utilize the food science expertise on its Foods Advisory Committee to help resolve scientific and policy issues related to food and cosmetics safety. It will also work to expand mutually beneficial arrangements on food science and food safety policy development with other agencies, academia, and industry. The Center anticipates that its arrangements and relationships with other organizations, including USDA, CDC, EPA, food associations, and state and local governments, will be critical to its efforts to effectively implement the food safety initiative.

Moreover, efforts to build and maintain the science base for foods and cosmetics through greater interagency coordination is consistent with the spirit and intent of the objectives of the President's National Science and Technology Council (NSTC). NSTC, which will coordinate interagency science and technology policy making process, will have a R&D coordinating committee on health, safety, and food.

Information Systems

The acquisition and proper use of the latest in computer and telecommunications technology must be a critical component of any strategy to more effectively regulate foods and cosmetics. In recent years, the Center has placed emphasis on using applications of these technologies to improve its ability to more efficiently collect, store, and analyze the ever increasing amounts of scientific, compliance, and other data required to make rapid and accurate regulatory decisions.

For FY 96 one of the Center's important goals will be to continue to implement improvements in telecommunications technology that will facilitate the electronic exchange of data (e.g., through public electronic bulletin boards) within the agency as well as with outside organizations. In order to achieve this goal the Center will promote the use of standardized nomenclatures and data architectures in food data bases to improve its ability to electronically transfer and receive data. These efforts will require expanded uses of CD-ROM and optical storage technology which are needed to electronically file, store, and retrieve, and disseminate large volumes of data.

Another goal will be to continue efforts to provide all Center employees with the latest in computing and telecommunications technology. Work efficiencies that can be achieved through expanded uses of PC technology are needed to help CFSAN meet its ever increasing regulatory responsibilities at a time when its staffing resource base is declining.

Organization and Management

A comprehensive reorganization of CFSAN was implemented at the beginning of FY 93. The restructured organization, which is product-oriented, is designed to permit closer integration and coordination between the Center's scientific and regulatory policy staffs. Also, the structure of the Food and Cosmetics Program was revised so that it would complement the new organizational structure. The program is now divided into 4 project areas: Chemical Safety of Foods, Microbiological Safety of Foods, Nutrient Quality and Food Labeling, and Cosmetic Safety and Labeling. The new project areas, which represent major areas of concern related to the regulation of foods and cosmetics, are designed to facilitate coordination between the Center's research and policy activities.

The new organizational structure and program structure were designed with the intent of putting the Center in a better position to meet the challenges posed by new safety issues, new legislative mandates, as well as existing and anticipated budgetary constraints. As necessary, CFSAN will periodically review current operations under both structures in order to identify opportunities for further refinements.

People, Facilities, and Equipment

FDA is currently recognized throughout the world as the premier food regulatory agency. If the Agency is to maintain its current position, it will need to have the resources, equipment, specialized expertise, etc., that are required to be a leading player in domestic and international food science research and food safety policy development.

Due to the budget constraints of the last few years, CFSAN has been unable to replace outdated scientific equipment and to acquire other new state-of-the-art scientific equipment at a rate that would insure that it has the capability to maintain its foods science and policy edge. At present, over 30% of CFSAN's \$18 to \$20 Million inventory of scientific equipment is past its scheduled date of replacement. At the current rate of replacement, by FY 96 over half of the scientific equipment inventory will be obsolete according to U.S. government standards. Furthermore, given the rapid advancements that are being achieved in the capabilities of scientific equipment, a significant percentage of the other scientific instrumentation will be technically obsolete even before its scheduled replacement date. If this trend in the gradual deterioration of the Center's scientific infrastructure is allowed to continue, the Agency's position as a leader in food safety could be seriously jeopardized.

Another important concern is the rate at which CFSAN's workforce is aging. With the current average age of 45, the Center could lose a substantial number of its more experienced policy and scientific staffs to retirement in the next several years. Such losses over

a relatively short period of time could severely hamper the Agency's ability to move forward with elements of the food safety initiative and other food and cosmetic related safety priorities.

In FY 96, CFSAN will need additional resources to help improve its scientific infrastructure. The Center plans to enhance the benefits gained from investments in scientific equipment and research facilities by continuing several other initiatives which will prevent a significant deterioration in the capability of its policy and scientific staffs. For instance, CFSAN will work with the Agency, the PHS, and the Department to determine ways it can improve its ability to attract and recruit employees, particularly research and review scientists. Other actions in this regard include the creation of a recruitment coordinator position, developing relationships with selected universities, and developing better recruitment materials. Moreover, the Center will work to develop an information base which will provide a better understanding of why Center employees leave before retirement, and use this knowledge to develop more effective methods to increase retention of employees.

Strategic Area: Post-Market

Program Activity: Food and Cosmetics

Strategic Goal:

Improve the Agency's ability to assure the safety sanitation, and wholesomeness of foods in the market place.

Discussion of Strategy to Achieve Goal:

Implement mandatory HACCP systems and other preventive measures in the food industry to minimize the potential for biological, chemical, and physical hazards in commercially processed foods.

Innovation:

HACCP is an innovation which offers an opportunity for FDA to significantly improve its ability to assure that foods available to American consumers are safe, sanitary, and wholesome. This system, which may be tailored to individual processing and distribution conditions, places emphasis on the prevention of contamination in processed foods. A properly designed HACCP system will permit the manufacturer to identify all potential safety and sanitation problems that could occur in the production and processing of a food and implement the necessary controls and monitoring procedures to prevent their occurrence. Another advantage is that, after the effectiveness of the HACCP systems are verified, the combination of routine monitoring inspection and reviews of production records will provide FDA a much better basis for evaluating the ongoing operations in the plant.

Performance Goal (#1):

Continue efforts to implement the regulation requiring mandatory HACCP systems in the domestic seafood industry.

Explanation of Goal:

It is estimated that there are 5,000 (approximately 1,500 high risk and 3,500 low risk) seafood establishments in the Agency's OEI. The proposed Seafood HACCP regulation will require that each of these establishments implement HACCP systems to assure the safety, sanitation, and wholesomeness of their product(s). Once this regulation becomes final, FDA must work with industry associations and state and local governments to advise firms of its requirements. Also, using revised inspection procedures which complement the HACCP approach, the Agency must review the HACCP plans for each establishment, conduct reviews of the operations (including determine the existence of the appropriate critical control points), review production records, and collect product samples, as necessary, to assure that the HACCP plans and practices are adequate. FDA must also assure that its

investigative force is trained in procedures for conducting HACCP inspections in seafood operations.

Performance Measure:

1. Implement an inspection program that will verify HACCP plans for approximately 65 percent of the domestic seafood establishments each year.

Current Level of Performance and Resources:

FDA currently devotes approximately 119 FTEs to the surveillance of domestic seafood establishments.* With these resources it is able to accomplish the following:

1. Conduct routine surveillance of 56% of the seafood establishments in the domestic inventory.
2. Collect and analyze product samples from approximately 30% of the establishments inspected.

Future Workload:

It is anticipated that the Seafood HACCP regulation is expected to take effect in January 1996. When the final rule is published, the Agency will need to begin in earnest efforts to prepare for its implementation. Some of the important activities that will occur from now through FY 96 are identified below:

1. In FY 94, conduct routine surveillance inspections of domestic seafood establishments. Develop and promulgate a final regulation on the mandatory seafood HACCP program. Develop and implement programs to train Agency investigators in the HACCP concept and work with industry to develop training programs for its personnel. In addition, hold meetings to brief industry, consumers, state and local officials, and other interested parties on the proposed HACCP regulation.
2. In FY 95, the Agency will work through industry associations and state and local governments to notify seafood establishments of the requirements under the new regulation. It will conduct routine surveillance inspections of domestic seafood establishments. During these inspections, investigators will assure that establishments are fully apprised of requirements under the new regulation, answer questions, and, as needed, provide guidance on the development of HACCP plans.

* Resources for the NSSP program are not included in these estimates.

The inspection strategy for seafood establishments will need to be revised to incorporate procedures to verify HACCP systems, including reviewing the HACCP plan, identifying and evaluating critical control points, and reviewing and evaluating production records. Field investigators will be trained in procedures for properly conducting HACCP inspections. In addition, the Agency will work with industry associations to develop training programs on HACCP systems for its members.

3. In early FY 96 there will be a continuation of efforts to work with firms to implement the new regulation. When the regulation officially takes effect (January 1996), FDA must begin to conduct inspections to verify the existence of HACCP systems in the seafood establishments.

Projected Performance with Current Resources and Future Workload:

At the current level of resources (approximately 119 FTEs), FDA will be able to accomplish the following:

1. Conduct verification inspections of 1,650 (33%) of the domestic seafood establishments to determine that HACCP systems are in-place, are being monitored properly, and that the appropriate records are being retained. These inspections will be targeted so that approximately 50% of the high risk establishments and 26% of the low risk establishments will be audited each year. This means that FDA will inspect high risk establishments every two years and low risk establishments every four years. (These estimates are based on the assumption that the verification inspection for a seafood establishment will require approximately 20 hours)
2. Collect and analyze 495 product samples from 30% of the establishments in which verification inspections are conducted. Sample collections and analyses will be reduced by 1/3 each year after the HACCP systems have been determined to be adequate.
3. Continue efforts to help industry understand and comply with the HACCP regulation for seafood.

Target Level of Performance and Resources:

While the Agency can implement provisions of the proposed Seafood HACCP regulation at the existing resource level, they will only support an inspection cycle which covers high risk establishments every two years and low risk establishments every four years. This inspection cycle is less than ideal because it would take up to four years for the Agency to assure that all seafood establishments have effective HACCP systems. Because of the need

to promptly verify that industry is meeting provisions of the Seafood regulation, a more reasonable strategy would be to cover high risk establishments every year and low risk establishments every other year. For FY 96, an additional 63 FD FTEs will be required to support this level of inspections. Because of reductions in the level of sample collections and analyses, the increase required for FY 97 will drop to 58 FD FTEs and to 45 FD FTEs in FY 98.

Since the food safety initiative envisions expanding mandatory HACCP to other industry segments over the next several years, there will be a continuing need for HACCP training and technical assistance. As the Agency moves forward with the implementation of HACCP in other industry segments, other investigators will need to be trained in basic HACCP principles and inspection procedures that are tailored to the specific industry. It is estimated that these activities will require an increase of 8 HQ FTEs and \$500 K. The additional FTE's will form a core group to provide training and technical assistance to FDA investigators when HACCP is expanded to other industry segments.

Also, technical assistance will be needed to help those firms, especially the smaller firms, which are having difficulty complying with the requirements of the new regulations. Experience with the pilot study for the seafood industry revealed that the Agency might expect to find that a high percentage of the HACCP plans (between 70% and 80%) might be found inadequate during the verification cycle. Since the benefits of HACCP are directly related to the quality of the plan and thoroughness of its implementation, being able to provide adequate levels of guidance and technical assistance to industry must be considered critical to the successful implementation of the HACCP program. An increase of 20 HQ FTEs and 10 FD FTEs will be needed to support these activities.

The following table provides estimates of the resources required to implement the proposed HACCP regulations for seafood based on the following assumptions: (1) a 20 hour inspection module, (2) an inspection cycle which covers high risk establishments every year and low risk establishments every 2 years, and (3) the need for modest training and technical assistance efforts.

Table 1 - Projected Performance with Additional Resources

Fiscal Year	93 Base	94	95	96	97	98
Performance Level: Percentage of seafood establishments covered each year	56%	56%	56%	65%	65%	65%
Total Resources: Supported FTEs:						
Center	20	20	20	48	48	48
Field	99	99	99	172	167	154
OC						
Total	119	119	119	220	215	202
Non-FTE \$				\$.5M	\$.5M	\$.5M

Performance Goal (#2): Expand mandatory HACCP systems to the next industry segments. At present the hard cheese and bakery industries are being considered for the next phase of HACCP, and a third industry will be named later. Since the specific mechanism that will be used to phase these industries into HACCP has not been determined and specific timeframes for the implementation of the systems have not been established, we do not have adequate information at this point to develop performance measures and resource estimates for FY 96.

Summary of Proposed Increases for FY 96

Agency Goal	HQ FTEs	FD FTEs	Dollars
Pre-Market Review	22	--	--
Post-Market Assurance			
Seafood HACCP	28	73	\$0.5 M
Nutrition Labeling	6	--	\$0.375 M
	<hr/> 34	<hr/> 73	<hr/> \$0.875 M
Science Base	20	6	\$4.0 M
Food Coordination	--	--	\$2.0 M
People, Facilities, \$ Equipment	--	--	\$1.5M
	<hr/>	<hr/>	<hr/>
Total, Food and Cosmetics	76	79	\$8.375M

Proposed Increases for FY 96

Pre-Market Review:

1. Reduce "Overdue" Petitions	20 HQ FTEs
2. Biotech Pre-market Notification	2 HQ FTEs
<hr/>	
Total Pre-Market	22 HQ FTEs

Post-Market Assurance:

1. Implement Proposed Seafood HACCP Regulation	
Verification Inspections (20 hour module/ 1 yr. high risk/2 yrs. low risk)	63 FD FTEs
Training and Technical Assistance	28 HQ FTEs 10 FD FTEs \$. 5 M
<hr/>	
Totals, Seafood HACCP	73 FD FTEs 28 HQ FTEs \$0.5 M

2. Nutrition Labeling:

Labeling Enforcement (State Contracts)	\$0.375 M
Nutrient Analyses	6 HQ FTEs
<hr/>	
Total, Nutrition Labeling	6 HQ FTEs \$0.375 M

Total Post-market Assurance:

34 HQ FTEs, 73 FD FTEs, \$0.375 State Contracts, &
\$0.5 M Operating Funds

Science Base (Inhouse Research and Contracts):

1.	Nutrition Analytical Methods	6 FD FTEs \$1.0 M
2.	Scientific Support for Petition Review	10 HQ FTEs \$1.0 M
3.	Processing/packaging technology innovations	10 HQ FTEs \$2.0 M
Total, Science Base		20 HQ FTEs 6 FD FTEs \$4.0 M

Food Coordination:

Food Code/foodborne disease problems in the retail food industry	\$2.0 M
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People, Facilities, and Equipment:

1.	Capital Reserve Account for Scientific Equipment	\$1.5 M
Total, People, Facilities, and Equipment		\$1.5 M

4/29/94

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE
 FOOD AND DRUG ADMINISTRATION
 5600 FISHERS LANE
 ROCKVILLE, MARYLAND 20857

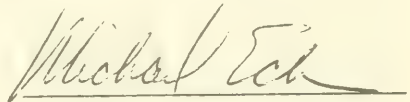
The Honorable Edolphus Towns
 Chairman, Subcommittee on Human Resources and
 Intergovernmental Relations
 B-372 Rayburn
 Washington, DC 20515
 Attn: Bill Larkin

THE MATERIAL ENCLOSED:

- ☐ may be of special interest to you
- ☒ responds to your recent request
- ☐ per conversation

FY 92 + 93 Summary Analytical Data

Should you have any questions regarding FDA activities,
 please give us a call at (Area code 301) 443-3793.



Office of Legislative Affairs

SUMMARY DATA
ANALYTICAL HOURS EXPENDED DURING FY 92 AND FY 93

	Operational FTE's	Supported FTE's
FY 92:		
Micro	102.2	184.0
Pest/tox	108.3	194.9
Other	157.1	282.8
FY 93:		
Micro	86.3	155.3
Pest/tox	121.2	218.2
Other	147.2	265.0

Data were obtained from end of year POVAC, Table 7A and where noted under the "ADJUST" column, POD-5 data were used to separate microbiological from chemical analysis.

A factor of 1.8 is used to adjust the operational FTE's to obtain supported FTE figures.

FY 92 TOTAL ANALYTICAL RESOURCE ACCOMPLISHMENTS FOR PMS 03 - 21							Total Samples	%
TYPE OF ANALYSIS	DOMESTIC ANALYSIS		IMPORT ANALYSIS		OPERATIONAL FTE'S	%		
	SAMPLES %	HOURS	SAMPLES %	HOURS				
MICROBIOLOGICAL	3022 37%	47694.9	7165 14	70339.9	102.2	27.8	1817	17%
PESTICIDES/ TOXIC ELEMENTS	12699 56%	72647	10256 26	52462	108.3	29.5	27355	37%
OTHER CHEMICAL	6873 30%	69190.7	21287 55	112289.1	157.1	42.7	26100	46%
TOTAL	22594	189532.6	38708	235091	367.6		45572	

FY 93 TOTAL ANALYTICAL RESOURCE ACCOMPLISHMENTS FOR PMS 03 - 21							Total Samples	%
TYPE OF ANALYSIS	DOMESTIC ANALYSIS		IMPORT ANALYSIS		OPERATIONAL FTE'S	%		
	SAMPLES	HOURS	SAMPLES	HOURS				
MICROBIOLOGICAL	3070 44	41858.2	5207 15	57664	86.2	24.3	6277	15
PESTICIDES/ TOXIC ELEMENTS	13372 50	90622	8042 23	49311	121.2	34.2	21414	38
OTHER CHEMICAL	5679 22	55632.2	21325 60	114415	147.2	41.5	27004	48
TOTAL	22121	188112.4	34574	221390	354.6		54195	

ROLL CALL

THE NEWSPAPER OF THE CAPITOL HILL

Food & Drug

Policy Briefing • May 23, 1994 • Second Section

Reforming A Flawed Approach To Food Safety

By Rep. Ed Towns

The federal government lacks any comprehensive food safety policy. That is the conclusion of the House Government Operations subcommittee on human resources and intergovernmental relations. In fact, the existing structure is ineffective, cumbersome and costly.

The numbers speak for themselves. According to the Centers for Disease Control and Prevention, food-borne disease kills at least 9,100 people each year while another 6.5 million become sick.

Because many cases go undiagnosed and unreported, the true extent of food-borne illness in the United States is probably much higher — 80 million by one estimate. The medical and other costs of food-borne illness are estimated to reach between \$4 billion and \$8 billion annually.

The current system did not develop under any national plan. Programs emerged piecemeal over the years, only, repetitive in response to specific economic or health threats.

Currently, 12 federal agencies spend about \$1 billion annually to administer about 35 laws governing food safety and quality.

The General Accounting Office (GAO) describes the current patchwork of federal food safety programs as illogical, inconsistent, inefficient, and ineffective.

The greatest problem is a bifurcated system that has yielded two different approaches to food safety, both of which have major flaws. The US Department of Agriculture (USDA) oversees meat and poultry and the Food and Drug Administration (FDA) oversees almost all other food products.

As early as 1977 a Senate report concluded that the division of responsibility between the USDA and FDA "has resulted in a regulatory program which is often duplicative, sometimes contradictory, undeniably costly, and unduly complex. There is no rationale, other than a historic one, to justify maintaining two separate, inconsistent, and costly systems for inspecting and otherwise regulating production of processed foods."

The USDA's meat and poultry inspection

program is obsolete, misleading, and incapable of protecting the public from harmful microbial contamination — the primary cause of food-borne illness.



Unaphoto

Since the turn of the century, USDA inspectors have been inspecting every animal carcass for obvious filth, spoilage, and disease. However, bacteria that make people sick easily escape the USDA's current sensory inspections because inspectors cannot see, feel, or smell microbial contamination.

The ground meat implicated in the E. coli O157:H7 outbreak in early 1993 that killed four children and made another 500 people sick passed the USDA's inspection. In fact, the USDA's inspections convey a false sense of security to consumers because the

USDA stamps every piece of inspected meat and poultry with a seal of approval even if the product is crawling with deadly bacteria.

The subcommittee's hearings last November revealed that despite being on notice for almost two decades, the USDA had failed to fix the fatal flaws in its inspection program. The National Academy of Sciences, GAO, and many others have repeatedly urged the USDA to replace its obsolete inspection program with a scientific, risk-based system to protect public health.

Yet witnesses after witness testified about the USDA's pattern of failure to act. Many witnesses testified that the USDA's primary mission to promote agriculture overshadows its responsibilities to protect consumers and

thwarts needed change. Recent allegations of USDA leniency toward the poultry industry raise anew the troubling appearance of conflict of interest, which undermines consumer health and confidence.

Although he inherited the problems, Secretary of Agriculture Mike Espy, in his career, has recognized the weaknesses in the USDA's programs and has undertaken several important initiatives, most notably requiring safe handling and cooking labels on raw meat and poultry products. After a 12-year hiatus on needed reform, the Secretary's efforts are highly commendable. However, earlier this year, the GAO concluded that while the USDA has made some changes,

Continued on page 18

Towns: We Need a Comprehensive Federal Food Safety Policy — and the Will to Act

Continued from page 1

"the inspection system is only marginally better today at protecting the public from harmful bacteria than it was a year ago, or even 87 years ago when it was first put in place."

The USDA has been unable to redirect its resources on microbial contamination because it is required by law to inspect every animal carcass regardless of the cost and futility of such an exercise.

The FDA suffers from its own problems. First, it is buried beneath several layers of bureaucracy within the Department of Health and Human Services, which diminishes its authority and prevents it from carrying out its responsibilities, according to the Edwards Committee, a 1991 blue-ribbon advisory panel.

The committee recommended elevating the agency's status within HHS to put the FDA on par with other regulatory agencies, such as the Environmental Protection Agency. The com-

mittee also proposed that if HHS failed to act, Congress should consider restructuring the FDA as a free-standing executive agency.

Second, both critics and supporters of the FDA have observed that a large disparity exists between the FDA's multiple food safety responsibilities and its available resources. Because of budget constraints, the FDA inspects facilities under its jurisdiction, on average, once every eight years, and that number is declining. The FDA inspected only one-third as many domestic food establishments in fiscal year 1992 as it did in fiscal year 1981.

With the rapid globalization of the food supply, the FDA's capacity to screen out unsafe imported food products is, at best, severely strained. The FDA recently began to shift its focus from end-product inspection to a Hazard Analysis Critical Control Point (HACCP) approach.

HACCP attempts to identify and analyze

likely hazards in a production process and then control these hazards at critical points in the process to prevent them from occurring.

But critics question whether the mandatory HACCP system for seafood that the FDA proposed earlier this year will be nothing more than a paper tiger because of limitations in the FDA's statutory authority — a third area of concern about the FDA.

Critics point out that the FDA generally cannot presume that firms are engaged in interstate commerce, require food processors to register, prohibit use of equipment that may contaminate food, or detain domestic products that violate food safety standards without obtaining a firm's voluntary cooperation or a court order.

To illustrate the disparity in the present system, consider how the federal government regulates food products derived from a dairy cow. The cow's milk is subject to FDA and state inspection, but after slaughtering, the cow's meat is subject to the USDA's inspection. But if the USDA finds a residue of an animal drug that exceeds a limit set by the FDA, then the USDA must refer the case to the FDA for regulatory action, which in turn must refer the case to the Department of Justice for possible criminal prosecution. Does this make any sense?

Real improvement in the nation's food safety system requires broad-based reform. Last September, Vice President Gore recommended an unprecedented consolidation and empowerment of federal food safety programs within the FDA.

I applaud the Vice President's leadership in this area. His recommendation addressed both the need to restructure the system to work efficiently and effectively and the need to accelerate the development of a scientific, risk-based food safety assurance program.

Although the Vice President's proposal is only the latest in a long list of proposals to reorganize federal food safety efforts, most of the suggestions have dealt with the organizational scheme and not the objectives of food safety programs or the need to streamline the federal bureaucracy.

For example, pending legislation would

separate marketing and inspection services and elevate food safety to an independent agency within USDA. However, the function would still reside within a department of agriculture, not a department of health. Moreover, how could we tell taxpayers that

Historically, we have revised our federal food safety system only in response to some crisis. But must we wait for the next tragedy if we can prevent it?

we streamlined government by creating not one, but two food safety commissions?

Simply changing organizational boxes will not save lives. We need a comprehensive federal food safety policy. The country is not at a loss for ideas on how to fix the current system. What is missing is the will to act. But the deadline has expired. The incidence of food-borne disease is getting worse, not better.

We must overcome our complacency, rise above our parochial interests, and work together to build a bold new vision of food protection centered on consumer health and well-being.

Historically, we have revised our federal food safety system only in response to some crisis. But must we wait for the next tragedy if we can prevent it?

The haunting words of Suzanne Kiner, whose daughter continues to suffer the effects from meat tainted with *E. coli* 0157:H7, still ring in my ears: "Have you ever planned a child's funeral?" This country must act to ensure that food is safe and not plan funerals for our children who die because we failed to act.

On Wednesday, the subcommittee on human resources and intergovernmental relations will continue to evaluate the Vice President's recommendation at a hearing focused on the FDA's role in food safety.

**Minnesota Department of Health**

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July 5, 1994

Mr. Bill Layden
Subcommittee on Human Resources and
Intergovernmental Relations
Congress of the United States
House of Representatives
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Layden:

I apologize for the delay in responding to you regarding our thoughts on the issue of foodborne disease in the United States. I hope that any information we can provide you may still be of use to you and the members of the subcommittee. I've enclosed a copy of a recent publication from our group detailing the epidemiology of foodborne disease in Minnesota. Specifically, we comment on a number of the questions which were presented to me in Representative Towns' letter to me of May 11.

If we can be of any additional assistance to you, please feel free to contact me. Best wishes.

Sincerely yours,

Michael T. Osterholm, Ph.D., M.P.H.
State Epidemiologist and Chief
Acute Disease Epidemiology Section

MTO:jw

STATE-OF-THE-ART CLINICAL ARTICLE

Changing Epidemiology of Food-Borne Disease: A Minnesota Perspective

Craig W. Hedberg, Kristine L. MacDonald,
and Michael T. Osterholm

*From the Acute Disease Epidemiology Section, Minnesota Department of
Health, Minneapolis, Minnesota*

Food, like water and air, is a basic human need. Furthermore, an abundant and varied supply of food can greatly enhance the quality of life. However, beyond providing energy, nutrients, and gastronomic delight, food is a potential vehicle for pathogenic microorganisms and their toxic products. To many, the concept of food-borne disease is primarily that of the classical picture of staphylococcal intoxication: the sudden onset of severe nausea, cramps, vomiting, and diarrhea that occurs 2 to 4 hours after eating food that has been left too long at room temperature. During the first half of this century, staphylococcal intoxication was the main type of food-borne disease recognized. Over the past 15 years, the epidemiology of food-borne disease has shifted. Increasingly, food-borne disease is being attributed to a wide variety of bacteria, parasites, and viruses. Today the risk of food-borne disease depends on the type of food, its production source, how it is prepared and handled, and the consuming host's resistance to the infectious agent. As these factors change, the epidemiology of food-borne diseases also necessarily changes.

The relationship between cardiovascular disease and consumption of saturated fat has led many Americans to abandon the traditional meat-and-potatoes diet that accompanied the postwar boom of the 1950s. The new American diet emphasizes fruits, vegetables, and grains and deemphasizes meats and foods with a high content of fat. The concept of a diet balanced between the four basic food groups has been replaced by a diet built on a food pyramid. Public information campaigns, such as Five-a-Day for Better Health from the National Cancer Institute, promote increased consumption of fresh fruits and vegetables. Progress has been made in promoting the heart-healthy diet during the past 30 years. However, these dietary changes have also altered the epidemiology of food-borne diseases in the United States.

In this review we discuss results of national surveillance of food-borne disease, the importance of national changes in the factors that contribute to the epidemiology of food-borne

disease (as illustrated by the results of food-borne disease surveillance at the Minnesota Department of Health), and issues of food safety for the 1990s and beyond. We focus primarily on investigations conducted in Minnesota because our recent experiences have demonstrated the importance of many of these factors. In addition, the fact that these outbreaks were recognized in Minnesota, a state with only 2% of the population of the United States, suggests that problems of food-borne disease are actually much more widespread.

Food-Borne Disease Surveillance

Estimates of the number of cases of food-borne disease in the United States range from 6.5 to 81 million cases per year, with from 525 to >7,000 food-borne-disease-associated deaths per year. Economic losses to ill persons, food producers, and the national economy have been estimated to be more than \$8 billion to \$23 billion annually. Better estimates are lacking, in part, because food-borne disease surveillance typically involves a series of events, only some of which are controlled by public health officials. First, an ill individual must seek and have access to medical care. Second, a clinician must obtain stool (or other appropriate clinical specimens) from the patient for microbial analysis. Third, the clinical laboratory must have the technical capability to evaluate the stool for the likely causative agent. Fourth, results of the stool culture and clinical information must be reported in a timely manner to state or local health departments. Finally, public health officials must have the resources to investigate the occurrence of the illness(es). A break at any step in this process will likely result in a failure to recognize the occurrence of food-borne disease.

The purpose of food-borne disease surveillance is to better understand the causes of food-borne disease, to develop and provide for implementation of appropriate control measures, and to detect trends in the epidemiology of food-borne disease. Outbreaks of food-borne disease are typically investigated by state or local health agencies and reported to the national food-borne disease surveillance system of the Centers for Disease Control and Prevention (CDC). From 1973 to 1987, 7,458 outbreaks involving 237,545 cases of food-borne disease in the United States were reported to the CDC. During this period, there was a decline in the proportion of outbreaks due to staphylococcal toxin and *Clostridium perfringens* and an increase in the proportion of out-

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breaks caused by *Salmonella* species. In addition, Norwalk virus, *Campylobacter jejuni*, *Escherichia coli* O157:H7, and *Listeria monocytogenes* emerged as important food-borne pathogens.

The number of outbreaks reported to the CDC peaked during 1982 and declined through 1987. It is unlikely that this decrease is due to an actual decrease in the incidence of food-borne disease in the community. The probable cause is related in part to the increased burdens placed by the epidemic of AIDS on the resources of state and local public health agencies and to the lack of support for the public health infrastructure.

Although national food-borne disease surveillance can be a powerful public health tool, the current system has limitations. Resource constraints affect the abilities of public health officials to adequately investigate small or even large outbreaks of food-borne disease, thus compounding the variability in reporting by type of pathogen. For example, during the 1980s, outbreaks due to *Clostridium botulinum* were reported more commonly to the CDC than were those due to *Campylobacter* species. In addition, the ability of laboratories to isolate and identify organisms in clinical specimens from patients and in implicated foods limits our awareness of the diversity of food-borne pathogens and the relative contribution of organisms that may not routinely be identified by clinical laboratories.

To illustrate recent trends in the occurrence of food-borne disease, we focused primarily on investigations conducted in Minnesota from 1978 through 1993. During this period, ~200 confirmed outbreaks of food-borne disease were investigated by local health departments and the Minnesota Department of Health. In ~10% of these investigations, the public health implications of our findings, with respect to the transmission, detection, and control of food-borne diseases, led to publication of the investigation report (table 1). The Minnesota Department of Health has attempted to aggressively identify and investigate the occurrence of food-borne disease during the past 15 years. Because of this aggressive approach, we believe that the trends evident from our statewide surveillance may be more representative of the true national picture than are data from many other states where resources for conducting such investigations are more limited.

Changes in the Factors That Contribute to the Epidemiology of Food-Borne Disease

Changes in several factors on a national level have contributed to changing the epidemiology of food-borne disease in the 1990s. First, changes in diet have resulted in changes in both the type and source of foods consumed. Increased consumption of food in commercial food service establishments has resulted in greater potential exposure to illnesses transmitted by food handlers. In addition, new methods of food

Table 1. Outbreaks of food-borne disease: selected investigations conducted by the Minnesota Department of Health, 1978–1993

Disease/agent	Vehicle	[Reference]
Brainerd diarrhea	Raw milk	[1]
Campylobacteriosis	Raw milk	[2]
Campylobacteriosis	Raw milk	[3]
Eosinophilia-myalgia syndrome	L-Tryptophan	[4]
<i>Escherichia coli</i> O157:H7 infection	Precooked ground beef patties	[5]
Giardiasis	Home-canned salmon	[6]
Giardiasis	Sandwiches	[7]
Hepatitis A	Relish	[8]
Norwalk gastroenteritis	Frosted bakery products	[9]
Norwalk gastroenteritis	Multiple cold food items	[10]
Norwalk-like gastroenteritis	Nonfrosted bakery products	[11]
Salmonellosis		
<i>S. newport</i>	Ground beef	[12]
<i>S. enteritidis</i>	Fast food	[13]
<i>S. poona</i>	Cantaloupes	[14]
<i>S. javiana</i>	Tomatoes	[15]
<i>S. javiana</i> and <i>S. oranienburg</i>	Cheese	[16]
<i>S. montevideo</i>	Tomatoes	Unpublished observations*
Shigellosis	Cold airline food	[17]
Thyrotoxicosis	Ground beef	[18]

NOTE: The outbreak investigations summarized in this table represent the work of many individuals and agencies in collaboration with the Minnesota Department of Health.

* J. W. McFarland, C. Hedberg, J. Besser-Wick, et al. (Minnesota Department of Health).

production have been developed along with large and complex networks of distribution. Within the context of these changes in society and industry, new infectious agents continue to emerge and new trends for known agents transmitted through food are recognized.

Changes in Diet

The changes in the American diet that have resulted in part from public health efforts to prevent cardiovascular disease (and more recently cancer) can be demonstrated by changes in the consumption of selected foods in the United States from 1970 to 1990 (table 2). During this period, average per capita consumption of whole milk declined 59% from 219 to 90 lb annually, and per capita consumption of red meat declined 15% from 132 to 112 lb. At the same time, per capita consumption of low fat milk, cheese, poultry, fresh vegetables, and fresh fruits increased 163% (50 to 131 lb), 117% (11 to 25 lb), 87% (34 to 64 lb), 29% (88 to 113 lb) and 16% (101 to 117 lb), respectively. Although these are national summary data based on the availability of foods in the marketplace, the decrease in saturated fat consumption

Table 2. Changes in per capita consumption of selected food items in the United States from 1970 through 1990.

Food item	Pounds of food		Change (%)
	1970	1990	
Whole milk	219	90	-59
Red meat	132	112	-15
Low fat milk	50	131	+163
Cheese	11	25	+117
Poultry	34	64	+87
Fresh vegetables	88	113	+29
Fresh fruit	101	117	+16

NOTE. Data provided by the Economic Research Service, United States Department of Agriculture.

predicted by these data is consistent with observed declines in levels of serum cholesterol in the community.

These dietary changes have coincided with dramatic increases in product availability in the United States. During the 1950s, the average grocery store in the United States stocked 300 food items on its shelves. By 1990, this number had increased 80-fold to 25,000 different food items. Currently, it is not uncommon to find grocery stores stocking over 50,000 different food items on their shelves, including hundreds of varieties of fresh fruits and vegetables, exotic seafood, grains, or food supplements.

The increased demand for fresh fruits and vegetables has also produced changes in the operation of food service establishments. Surveys conducted by the National Restaurant Association found that salad bars and separate sections for smokers and nonsmokers have become two of the most frequently sought features in a restaurant. By 1988, 71% of fast-food and family restaurant chains offered salads or salad bars. Meeting the increased demand for fresh fruits and vegetables in the United States has required the seasonal importation of produce from Mexico, Central America, and other tropical areas. Seasonally, >75% of fresh fruits and vegetables are harvested outside the United States and delivered within days to grocery stores and restaurants (table 3). During the winter months from 1989 through 1992, 33% to 70% of cantaloupes, 57% to 72% of green onions, 69% to 79% of cucumbers, and 20% to 64% of tomatoes purchased by consumers in the United States were harvested in Mexico. With the pending formation of a free trade zone between Mexico, the United States, and Canada, it is likely that produce imports from Mexico into the United States will increase substantially in the future. Competition between producers in the United States and in foreign countries may also result in cost-cutting measures in agricultural areas in the United States that already rely on low-paid migrant workers. These factors increase the potential for produce to become contaminated in the field, during packing, or during distribution to retail markets.

The other side of Five-a-Day for Better Health. One result of the increased consumption of fresh fruits and vegetables has been the recent occurrence of large outbreaks of hepatitis A, shigellosis, and salmonellosis due to the widespread distribution of fresh produce items. Although outbreaks of salmonellosis associated with fresh fruits and vegetables traditionally have been rare, four multistate outbreaks of salmonellosis, each involving 100 to 400 confirmed cases, have been attributed to fresh fruit or vegetable sources since 1990; three outbreaks occurred in Minnesota. Two outbreaks (one of *Salmonella chester* in 1990 and one of *Salmonella poona* in 1991) involved consumption of cantaloupes, and two outbreaks (one of *Salmonella javiana* in 1990 and one of *Salmonella montevideo* in 1993) involved consumption of tomatoes.

All of these outbreaks were recognized through statewide surveillance by public health laboratories of *Salmonella* serotypes isolated from humans. The unusual occurrence of an uncommon serotype prompted state health officials to investigate the source of the infections. In each outbreak, results of extensive epidemiologic studies implicated the food item and indicated its probable source of origin. In none of these outbreaks were the outbreak-associated organisms isolated from the implicated fruit or vegetable; most of the implicated food products had been consumed or discarded before investigation. However, following the identification of cantaloupes from Mexico as the source for the *S. chester* outbreak, investigators from the United States Food and Drug Administration (FDA) conducted bacteriologic sampling of imported cantaloupes and watermelons entering at the Mexico-United States border. The FDA isolated numerous serotypes of *Salmonella* from ~1% of the rinds.

Investigation of the *S. poona* outbreak in Minnesota implicated cantaloupes shipped from an agricultural area in the lower Rio Grande area of Texas as the source. Illness was associated with cantaloupe in salad bars or in fruit salads but not with fresh sliced cantaloupe. This fact suggests that temperature abuse of the contaminated fruit may have resulted in increased pathogen load after the fruit was at room temperature for several hours. Since no common restaurants were

Table 3. Percent of selected produce items from Mexico sold in the United States by quarter, 1989-1992.

Quarter	Cantaloupe	Green onion	Cucumber	Tomato
January-March	33-70	57-72	69-79	20-64
April-June	23-40	33-51	15-17	10-30
July-September	0-1	4-20	1	4-8
October-December	9-28	30-45	23-26	5-13
Total	14-20	30-47	27-28	10-20

NOTE. Data are from the Agricultural Marketing Service, United States Department of Agriculture.

identified by patients with *S. poona* infection and because of the widespread distribution of cases, we believe that autologous cross-contamination of the fruit from the rind occurred. The extra handling required to prepare fruit salads and salad bars may have increased the potential for contaminating the fruit from the rind.

These outbreaks demonstrate the emerging potential for food-borne disease associated with fresh fruits and vegetables. Important epidemiologic features of these outbreaks included the absence of recognized clusters of cases associated with households or food service establishments despite the distribution of the implicated food items through both sources, the widespread geographic distribution of outbreak-associated cases, and the apparent sporadic or low-level contamination of the implicated food items. Only the temporal clustering of these unusual *Salmonella* serotypes made it possible to detect the occurrence of these outbreaks.

Delay in the recognition of these outbreaks made it difficult to trace the source of the implicated produce, thus precluding us from determining how the produce was contaminated or what corrective measures were needed to prevent the recurrence of similar outbreaks. Tomatoes are transported and stored at temperatures of 55°F to 60°F and are frequently eaten raw. Cantaloupes are grown on the ground and may be contaminated on their surface with dirt, chemicals, animal excreta, and pathogenic bacteria. The FDA developed specific recommendations for handling melons following these outbreaks after they sampled imported melons. One of these recommendations, thoroughly cleaning the surface of melons and all fruits and vegetables before they are handled and consumed, appears to be prudent. However, the potential efficacy of this recommendation is unknown. Given national trends toward consumption of fresh fruits and vegetables, these outbreaks are likely to occur more frequently in the future.

Increased Consumption of Food in Commercial Food Service Establishments

Along with changing diets, Americans have increased their consumption of food from commercial food service establishments. From 1972 to 1989, the number of restaurants in the United States with table service increased from 112,000 to 161,000. In addition, the number of fast-food restaurants doubled from 73,000 in 1972 to >146,000 in 1989. Of \$564 billion spent for food in the United States in 1990, 37% was spent away from home in a commercial food establishment. Coupled with the increased consumption of fresh fruits and vegetables, the growth in the number of food service establishments has resulted in even greater consumption of cold food items prepared by hand by workers in commercial kitchens.

In 1990, ~10 million persons were employed in the food service industry. Typically, wages for food service workers

are low, and benefits and advancement opportunities are lacking. In most situations, these workers receive no additional benefit package (no insurance, no sick leave, and no paid vacation). Because nationwide many employers in the food service business experience labor shortages, food handlers are often hired without regard for training in proper sanitation and hygiene. In addition, 38% of individuals employed in food service occupations in 1988 had not completed high school, compared with 14% of all employed individuals. Finally, the turnover rate in food service occupations is high; 42% of all food service employees in 1990 had worked for their current employer for <1 year, thus making it difficult to provide on-the-job training regarding hygiene and sanitation.

Several outbreaks of food-borne disease in Minnesota demonstrate the importance of contamination of food items by food handlers in a variety of food service settings. These outbreaks include viral gastroenteritis associated with bakery products, giardiasis associated with home-canned salmon, salmonellosis associated with a fast-food restaurant, and shigellosis associated with cold food items served on a commercial airline.

The potential for efficient transmission of a pathogen with a low infective dose in cold food items was demonstrated by two outbreaks of Norwalk or Norwalk-like gastroenteritis; in these outbreaks, bakery employees vomited at work and subsequently contaminated 76 L of butter cream frosting in one outbreak and several hundred hamburger buns and oatmeal cookies in another. Attack rates of at least 60% were observed among persons who ate the frosted bakery products, of which 10,000 were sold to the public. In the other outbreak, the observed attack rates were <30% among persons who ate contaminated bakery products that were not frosted. The transmission of Norwalk-like viruses among food service workers can lead to outbreaks of viral gastroenteritis that can persist at an establishment for >1 week. In fact, such transmission appears to be common in outbreaks of viral gastroenteritis. More than one ill food handler was identified in 14 (78%) of 18 restaurant-based food-borne outbreaks of viral gastroenteritis in Minnesota from 1984 to 1991. In six (43%) of these 14 outbreaks, the restaurant voluntarily closed for 72 hours because of the evidence of ongoing transmission to patrons.

Another outbreak that demonstrated efficient transmission and a low infective dose was an outbreak of giardiasis associated with home-canned salmon. Twenty-nine (48%) of 60 employees of a high school developed giardiasis between 2 and 23 November 1979. Epidemiologic investigation implicated consumption of home-canned salmon that was served in employees' lounges on 29 October. The wife of an employee had handled the salmon briefly while transferring it from the canning jars to plastic containers. She became ill with giardiasis 19 days after the salmon was served at the school. However, before transferring the salmon she had dia-

pered her 12-month-old grandson. He was subsequently shown to be an asymptomatic carrier of *Giardia lamblia*. Although she reported washing her hands after diapering her grandson, she was observed to have good hygiene, and the typical amount of salmon consumed by employees was only about one tablespoon, a large proportion of employees who ate the salmon became ill. Reported outbreaks of food-borne giardiasis are uncommon. However, the uncommonness may be due more to the long and variable incubation period, which makes recognition of an outbreak difficult, than to the actual frequency of their occurrence.

The transmission of salmonellosis by food handlers has not been recognized as being important. However, in September 1989, an outbreak of infection with *Salmonella enteritidis* occurred in patrons and employees of a fast-food restaurant in which growth of *Salmonella* on implicated food items was unlikely. Transmission took place over a 9-day period. A single employee who had onset of gastrointestinal illness 1 day before the first reported patron exposures was identified. A case-control study demonstrated that food items handled by this employee were associated with illness. Rates of illness ranged from 0.6% to 2.9% among patrons who ate during hours that the employee worked. Other employees also became ill after eating food handled by the implicated employee. Transmission of illness to patrons continued after the employee stopped working, apparently as a result of additional infected food handlers contaminating sandwiches.

Food handlers with asymptomatic or mild infections with *Shigella sonnei* may have contributed to transmission over a 1-month period in an outbreak of shigellosis associated with consumption of food on a Minnesota-based commercial airline. In October 1988, a local newspaper reported the occurrence of diarrheal illness among members of a Minnesota-based professional football team. Results of a cohort study of team members implicated cold sandwiches prepared in the Twin Cities at the airline's flight kitchen. Temperature abuse of the sandwiches between their preparation on Friday and consumption on Sunday probably allowed growth of *Shigella* and resulted in the relatively high attack rate among football players.

Subsequently, confirmed or probable shigellosis was identified among 240 passengers on 219 flights to 24 states, the District of Columbia, and four countries between 14 September and 13 October. An outbreak-associated strain of *S. sonnei* was isolated from football players and accompanying staff, airline passengers, and flight attendants. Thirty (4.1%) of 725 passengers on 13 flights with confirmed cases had confirmed or probable shigellosis. We estimated that at least 1,900 cases of shigellosis occurred among airline passengers during this outbreak. Illness was associated with consumption of cold food items served on the flights and prepared by hand at the airline's flight kitchen. Food items were likely contaminated during processing by one or more food handlers who acquired *S. sonnei* infection in the community.

The larger outbreak was recognized only because of the outbreak among the professional football team members. Given the relatively low attack rate among passengers on scheduled flights, long incubation periods, and dispersion of ill individuals, recognition of this outbreak (or similar outbreaks) by routine surveillance methods such as reporting of cases of shigella infection to the CDC would have been virtually impossible.

New Methods of Food Production

Fresh fruits, vegetables, and other cold food items are now being mass produced and distributed through large and complex networks of distribution. The size and complexity of these operations can greatly magnify the public health significance of food-borne contamination.

The airline-associated outbreak of shigellosis is a case in point. The flight kitchen prepared 100,000 meals per week in an assembly-line fashion in a modern physical plant. Recipes and practices of food preparation had been analyzed for identification of potential hazards. Critical points to control these hazards were identified and monitored. This use of hazard analysis and critical control point evaluations represented the state of the art in food safety. However, the facility received an unsatisfactory sanitation rating, and major deficiencies in hand washing and food handling practices were noted.

The preparation cycle for meals, from initial preparation of ingredients to service on the airplane, frequently encompassed 2 to 3 days. The distribution of job responsibilities allowed individual food handlers to handle cold food items eaten by thousands of airline passengers and airline flight personnel. Although the flight kitchen provided a sick leave benefit, employees were required to have worked 90 days before becoming eligible for this benefit. The median duration of employment for 81 food handlers who were interviewed was 10 months (range, 1 week to 6 years). Several food handlers admitted to working while they were ill with diarrhea. However, due in part to the delay in recognition of the outbreak, none of the food handlers were shown to be infected with *S. sonnei*. The flight kitchen was designed to be a state-of-the-art facility. However, an apparent failure to adequately train and supervise food handlers on the production lines led to the occurrence of this outbreak.

In the modern world of food production and distribution, even relatively small producers become part of large and complex networks of food distribution. This type of distribution network can magnify the outbreak potential of events that may appear to be highly localized. An example of this is a multistate outbreak of infections with *S. javiana* and *Salmonella oranienburg* that occurred due to consumption of contaminated mozzarella cheese and shredded cheese products. As with the fruit- and vegetable-associated outbreaks of salmonellosis, this outbreak was only identified due to an in-

creased incidence of human infection with an unusual *Salmonella* serotype in Minnesota. After an initial case-control study implicated cheese as the source of the outbreak, a second case-control study confirmed that cases were more likely than controls to have consumed mozzarella cheese manufactured at a single cheese plant in Wisconsin or cheese that had been shredded at processing plants that also shredded cheese manufactured at the implicated mozzarella cheese plant. The outbreak-associated strains of both serotypes were isolated from two unopened 16-oz blocks of mozzarella cheese produced at the implicated plant. The most probable numbers of *Salmonella* organisms in these samples were 0.36/100 g (1.6/lb) and 4.3/100 g (19.5/lb). These low levels of contamination made the microbiological assessment of cheese samples very difficult. The implicated mozzarella cheese plant produced and distributed ~5.25 million lb of cheese between March and May 1989. It went bankrupt in May 1989. Although this plant was relatively small by industry standards, the distribution of its cheese to four large processors who subsequently shred it and thereby contaminated cheeses from other sources led to a widespread outbreak of salmonellosis.

Implications for sporadic or low-level contamination. During the 1950s, food-borne outbreaks were recognized because of high attack rates, short incubation periods, and their occurrence in defined groups. In contrast, mass-produced food items with sporadic or low-level contamination may be distributed to thousands of people living hundreds of miles from the source. These outbreaks typically involve low attack rates, often <5% among those consuming the implicated product. However, they assume major importance due to the very large numbers of persons exposed to the bulk product produced. The human consumer appears to have become the ultimate bioassay for low-level or sporadic contamination of our food supply. Today, contaminated food products with a level of contamination capable of infecting only one in 10,000 exposed persons (infective dose [ID]_{0.001}) take on as much public health importance as those with an ID₅₀ of yesterday.

New food technologies. In attempts to improve the convenience and quality of foods served in a variety of settings, cook-freeze, cook-chill, and minimally processed chilled foods are being developed and distributed. The potential for these foods to serve as vehicles for food-borne disease depends on the source and handling of the product as well as the consumer. In October 1988, 32 cases of bloody diarrhea or culture-confirmed infection with *E. coli* O157:H7 were identified among 1,562 students at a junior high school. A case-control study revealed that cases were more likely than controls to have eaten precooked hamburger patties in the school cafeteria on a specific day. The estimated attack rate among students who ate these hamburgers was 8%. The patties should have been sufficiently cooked by the manufacturer so that enteric pathogens were destroyed before they

were frozen and distributed. Consumers do not typically consider these products uncooked since they appear to be similar to other precooked deli meats. However, *E. coli* organisms were cultured from frozen patties that were manufactured at the same plant on the same dates as the implicated patties, but serotype O157:H7 was not isolated. The reason for lack of cooking, or the frequency with which it occurred, was unclear. This outbreak demonstrated that precooked hamburger patties may serve as vehicles for *E. coli* O157:H7 infection. During a 12-month period in 1986 and 1987, more than 2 million of the 3.8 billion lb of raw hamburger produced in the United States were heat processed before distribution. Despite the findings of our investigation of this outbreak, there are currently no federal or state regulatory standards that ensure the safety of heat-processed uncured hamburger patties.

Products of microbial fermentation have been consumed by humans for thousands of years. Increasingly, highly selected and genetically engineered bacteria and fungi are being used in the development of new products and manufacturing processes. In 1989, we documented an outbreak of eosinophilia-myalgia syndrome (EMS), a recently described disease that was associated with such a product. EMS is characterized by marked peripheral eosinophilia with scleroderma-like features. Cases had occurred and patients had sought medical attention for several years before physicians in New Mexico and Minnesota reported that three patients with EMS had all consumed products containing tryptophan before the onset of their illnesses. Within several days of recognizing the occurrence of a cluster of such cases in Minnesota, we completed a case-control study that demonstrated an association between consumption of products with tryptophan and EMS. Following a similar study in New Mexico and a reported death of a patient with EMS in New York, the FDA ordered a recall of these products. Clinical features of the illness did not suggest a food-borne etiology, cases were geographically widespread, the outbreak had been occurring for >6 months before it was recognized, epidemiologic investigation identified the source of the outbreak, and the outbreak was controlled by the removal of tryptophan from the marketplace.

Epidemiologic investigations implicated consumption of tryptophan manufactured by a single Japanese company as the source of the outbreak. This company used a fermentation process involving *Bacillus amyloliquefaciens* to manufacture tryptophan. Analysis of the manufacturing conditions according to the retail lot demonstrated an association between lots consumed by individual cases and the use of reduced quantities of powdered carbon in a purification step as well as the use of a new strain of *B. amyloliquefaciens* (strain V). There was a significant correlation between the reduced amount of powdered carbon used during manufacturing and the use of the new bacterial strain. High-performance liquid chromatography of this company's tryptophan

demonstrated one absorbance peak that was present in nine of 12 retail lots used by cases and three of 11 lots used by controls. It was later determined that the structure of this peak was 1,1'-ethylidenebis(tryptophan).

Our data suggest that the outbreak in 1989 was caused by tryptophan-containing 1,1'-ethylidenebis(tryptophan) or another unidentified contaminant. Furthermore, the implicated tryptophan was manufactured by a single company under specific operating conditions that had changed shortly before the occurrence of the outbreak. Reduction in the use of powdered carbon may have allowed more of the etiologic agent to remain in the final product. The use of *B. amyloliquefaciens* strain V may have produced larger quantities of the etiologic agent than did the use of earlier strains. However, studies conducted by the company suggested that strain V differed from previous strains only in its genetically enhanced ability to synthesize serine and 5-phosphoribosyl-1-pyrophosphate. The role of genetically altered bacteria in this outbreak is not presently known but cannot be discounted.

New Infectious Agents

With each decade since the development of national food-borne disease surveillance, the list of recognized food-borne enteropathogens has expanded. During the 1960s, *C. perfringens* was identified as a food-borne pathogen of major significance. During the 1970s, Norwalk virus was identified as the primary cause of outbreaks of acute infectious nonbacterial gastroenteritis in the United States. During the 1980s, *Campylobacter* was recognized as an important cause of outbreaks associated with the consumption of raw milk and poultry, and *L. monocytogenes* and *E. coli* O157:H7 were reported as food-borne pathogens.

E. coli O157:H7. The emergence of a new pathogen may have regional, national, or global significance depending on the nature of the agent and how and where it enters the food supply. Some organisms emerge into the awareness of the medical and public health communities because investigators begin to conduct surveillance and laboratory studies to identify them (e.g., *Campylobacter*, *Listeria*). *E. coli* O157:H7 and other verotoxin-producing *E. coli* appear to be relatively new food-borne pathogens that are emerging as major public health problems. Nationally, the first outbreaks of hemorrhagic colitis due to *E. coli* O157:H7 were reported in 1983. These and several subsequently reported outbreaks were associated with the consumption of inadequately cooked ground beef. In addition to increasingly frequent reports of food-borne outbreaks due to *E. coli* O157:H7 infection, evidence of the emerging nature of this pathogen is demonstrated by surveillance for hemolytic-uremic syndrome (HUS).

From 1979 through 1988, 117 patients with HUS were identified through review of medical records from all hospi-

tals in Minnesota. Four children died and 27 suffered serious complications. *E. coli* O157:H7 was isolated from 13 (46%) of 28 patients whose stool was submitted for examination for this pathogen. The incidence of HUS increased from 0.5 cases per 100,000 child-years among children <18 years of age in 1979 (six cases) to 2.0 cases per 100,000 child-years in 1988 (28 cases). The dramatic increase in HUS cases suggests an actual increase in the occurrence of *E. coli* O157:H7 during this period.

E. coli O157:H7 and HUS have been reportable in Minnesota since 1988. The number of cases of infection with *E. coli* O157:H7 reported to the Minnesota Department of Health increased from 48 in 1989 to 129 in 1992. In contrast, the number of HUS cases reported to the Minnesota Department of Health decreased from 28 in 1988 to nine in 1991 and 1992. We believe that the increase in cases of *E. coli* O157:H7 infection that was concurrent with a decrease in HUS cases was due to the increasing availability of laboratory testing for *E. coli* O157:H7 in Minnesota during this period. Nonetheless, only 28% of major clinical microbiology laboratories in Minnesota surveyed during 1992 screened for *E. coli* O157:H7. As many as one-third of *E. coli* O157:H7 infections in persons who sought medical attention and from whom stool specimens were collected during 1992 may have gone unrecognized due to lack of appropriate laboratory testing and reporting. Until laboratories routinely culture all stool specimens for *E. coli* O157:H7, until *E. coli* O157:H7 and HUS are made reportable in all states, and until national surveillance is implemented, it will be difficult to evaluate trends in the occurrence of these diseases and the impact of public health measures to reduce their occurrence.

S. enteritidis and eggs. The emergence of egg-associated *S. enteritidis* infection in the United States demonstrates that the epidemiology of illness caused by well-known pathogens is subject to change. During 1988, investigators from the CDC and several eastern state health departments reported a sevenfold increase in the rate of *S. enteritidis* infections between 1976 and 1986 in the northeastern United States. In addition, they noted a large increase in the number of *S. enteritidis* outbreaks associated with the consumption of eggs and egg-containing foods. The sources of eggs associated with a number of these outbreaks were traced to several large farms where laying hens infected with *S. enteritidis* were identified.

In Minnesota, where *S. enteritidis* has historically been one of the most common serotypes of *Salmonella*, the incidence of reported *S. enteritidis* infections doubled from 1.0 per 100,000 person-years from 1980 to 1983 to 2.4 per 100,000 person-years from 1987 to 1990. However, no egg-associated outbreaks of salmonellosis have been identified in Minnesota. A case-control study of adults in Minnesota that was conducted during 1989 and 1990 demonstrated that sporadic cases of both *S. enteritidis* infection and *Salmonella typhimurium* infection were more likely to have consumed

undercooked eggs or egg-containing foods during the 3 days before the onset of illness than were controls during a similar reference period. The frequent consumption of individual fried eggs by cases in this study suggests that the inoculum in the egg at the moment it was cracked into the frying pan was sufficient to cause infection. The proportion of reported sporadic cases of salmonellosis among adults in Minnesota that were attributable to the consumption of undercooked eggs was 37% for *S. enteritidis* infection and 16% for *S. typhimurium* infection. Our findings demonstrate that eggs are an important vehicle for *S. enteritidis* and *S. typhimurium*, even in the absence of recognized outbreaks, and may have a broader role in the epidemiology of human salmonellosis.

Food-borne diseases with atypical clinical presentation. Three separate outbreaks demonstrate the occurrence of novel food-borne diseases that were not initially suspected because the clinical presentation was not typical of food-borne disease. The first was an outbreak of Brainerd diarrhea, a previously undescribed chronic diarrhea syndrome that affected 122 residents of Brainerd, Minnesota, between December 1983 and July 1984. The illness lasted at least 1 year for 75% of cases and was characterized by acute onset, marked urgency, a lack of systemic symptoms, and a failure to respond to antimicrobial agents. Consumption of raw milk from a single dairy was associated with the illness. Extensive laboratory examination did not identify an etiologic agent. The outbreak went unrecognized for 6 months before clinicians suspected the possibility of a common relationship between the patients. Following the description of this outbreak, numerous other outbreaks in the United States that were similar in epidemiology were recognized to have occurred both before and after this one occurred. In addition to raw milk, two outbreaks of Brainerd diarrhea were associated with contaminated water. This illness appears to represent a previously unrecognized but important clinical entity.

Similarly, an outbreak of thyrotoxicosis caused by the consumption of bovine thyroid glands in ground beef occurred between April 1984 and August 1985 among residents of southwestern Minnesota and adjacent areas of South Dakota and Iowa. One hundred twenty-one cases were identified through surveillance of medical clinics, laboratories, hospitals, and physician's offices. A case-control study implicated ground beef patties prepared from neck trimmings from a local beef slaughter plant. The cause of the outbreak was confirmed by the findings of bovine thyroid tissue in samples of beef trimmings from the plant, high concentrations of thyroid hormone in case samples but not in control samples of ground beef, and the demonstration of prompt increases in concentrations of serum thyroid hormone in volunteers who ate the implicated ground beef. The outbreak ended after gullet trimming was discontinued at the plant. The practice was subsequently prohibited by the United States Department of Agriculture (USDA). The clinical features of the illness suggested the diagnosis of silent thyroiditis, and it is

possible that sporadic cases, or even outbreaks, of thyrotoxicosis factitia caused by this mechanism may have occurred in the past but were not recognized.

A final outbreak that brings together many of the issues previously discussed is the occurrence of EMS. This outbreak demonstrates that public health action based on results of epidemiologic investigation can prevent occurrence of disease, even when the specific pathogens or other causative agents cannot be identified.

The occurrence of these outbreaks suggests that other diseases in our communities today could be due to the consumption of contaminated food but are not recognized as such. Thus, general disease surveillance and outbreak investigations are critical to understanding the pathogenesis of disease.

Food Safety Issues for the 1990s and Beyond

Requirements of Public Health Surveillance

Low-level contamination of mass-produced or distributed food products poses considerable challenges to public health surveillance of food-borne disease. Responding to these challenges requires redefining infectious disease surveillance in this country and providing the infrastructure support to carry out that surveillance activity.

Consumers who become ill (whether related to airline food, cantaloupes, cheese, tomatoes, or any of the more common vehicles of food-borne disease) and clinicians need to be aware of the potential for food-borne illness. However, the current cost-containment climate in health care may mean that clinicians and their patients will be less likely to request or obtain appropriate stool samples for culture. For any surveillance system for food-borne disease to succeed, clinicians must act on their clinical suspicions and notify local or state health departments. In addition, the public health infrastructure needs to be capable of responding to these reports by providing both the laboratory resources to confirm the agent and the epidemiologic resources to investigate the potential outbreak, no matter how small or localized it may seem. As demonstrated by airline-associated shigellosis, investigating a small outbreak may be the key to identifying a very large outbreak. In turn, this investigation may lead to the prevention of numerous additional cases of disease.

Epidemiologists must work with laboratorians to develop new detection and identification methods, evaluate the results of existing methods, and increase the likelihood for the productive use of limited public health resources. However, epidemiologists should not be constrained by the lack of laboratory support when epidemiologic results provide a clear description of events. Epidemiologic methods may be inherently more sensitive than bacteriologic methods in identifying the source of outbreaks resulting from the sporadic or low-level contamination of a widely distributed food prod-

uct. Therefore, FDA and state regulators should consider epidemiologic results as sufficient grounds for initiating and determining the scope of product recalls.

Developing and maintaining a public health infrastructure capable of conducting surveillance for food-borne disease is a key issue of food safety for the 1990s. As described above, the epidemiologic requirements and the need for laboratory support of food-borne disease surveillance are substantial. However, coordinated surveillance efforts on the local, state, and national levels are critical for detecting changes in the occurrence of food-borne disease. Currently, there is no federal categorical support for food-borne disease such as there is for AIDS, tuberculosis, sexually transmitted diseases, and vaccine-preventable diseases. As new agents (such as *E. coli* O157:H7) enter the food supply, as the scale of production of cold food items increases (such as in the flight kitchen involved with the outbreak of shigellosis), and as distribution networks for food items become more complex (such as in the distribution of cheese contaminated with *S. javiana* and *S. oranienburg*), a dedicated surveillance system is needed for identifying problems and suggesting potential strategies that will control and prevent similar occurrences in the future.

The American diet has changed in response to concerns relating diet to health. The increased demand for fresh fruits and vegetables has increased the potential for exposure to a wide variety of enteric pathogens, both foreign and domestic. The cumulative magnitude of exposure is such that even sporadic or low-level contamination of individual food items results in a significant public health burden of enteric disease. Interventions aimed at improving hygienic conditions in the production of fresh fruits and vegetables and improving food handling practices on the part of individual consumers may reduce the risk of food-borne disease associated with these foods. However, the use of new technologies, such as irradiation to pasteurize fruits, vegetables, and raw meat and poultry products, may play a critical role in ensuring the microbial safety of the food supply in the future.

The Consumer and Health Education

The final control in any system of food safety is the consumer. In a free society, individuals may choose to put themselves at risk for food-borne disease by eating undercooked eggs or undercooked hamburger or by drinking raw milk. However, the public health community should strive to eliminate unexpected hazards and make risk-taking choices informed ones. In 1969, a report of the USDA and FDA identified eggs as an important source of *Salmonella*. In October 1988, the Minnesota Department of Health and the Minnesota Department of Agriculture issued a joint news release advising against consumption of raw eggs because of the risk of acquiring salmonellosis. Despite this effort, only 17% of cases and 14% of controls enrolled in the case-control study

of sporadic salmonellal infections during 1989 to 1990 identified eggs as a potential source of *Salmonella*.

Media publicity of food-borne disease problems can heighten the public's awareness. However, information does not immediately lead to behavior change. This circumstance may be due in part to the optimistic view that people have that they are less likely to develop a food-borne illness than is someone else. Food safety officials concerned with changing the eating behaviors of the public need to adapt the models of behavior change that have helped reduce cardiovascular disease risks in the population, particularly as they relate to diet.

In conclusion, the public health agenda for the 1990s must include a comprehensive review of food safety. We must develop and support new regulatory and public health programs to prevent food-borne disease that are tailored to the unique aspects of producing, processing, and distributing food in the 1990s. Those of us in the public health field must accept, as part of any basic public health program, responsibility for disease surveillance, and we must pursue the necessary resources for rapid investigation of potential outbreaks.

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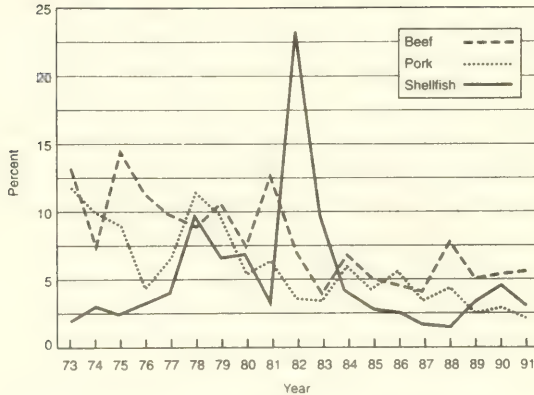


Figure C.1. Abstract cover graph (adapted from Bean and Griffin, 1990; Bean, pers. com., 1994). Percentage of foodborne disease outbreaks with known vehicle associated with beef, pork, and shellfish, by year, 1973–1991. Variation in vehicles for foodborne pathogens over time is caused by several factors, which include

- random fluctuations in pathogen detection because only a fraction of all outbreaks are reported,
- improvement in test sensitivity and epidemiology that enables new foodborne pathogens to be identified or increases the probability of pathogen detections,
- changes in production, processing, marketing, and consumption practices that alter human exposure over time,
- evolutionary changes in pathogens and alteration in their niches causing different foods to become pathogen vehicles at different times, and
- regulatory actions successful in controlling pathogens and reducing the incidence from particular food sources.

See Bean and Griffin (1990) for more detail about annual variations in pathogen-food relationships. The 1988–1991 data was provided by Dr. Nancy H. Bean, Centers for Disease Control and Prevention, Atlanta, Georgia.

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Contents

Interpretive Summary	1
Task Force Findings, 1	
Recommendations for Reducing Foodborne Illness, 1	
Summary	3
Charge to the Task Force, 3	
Task Force Findings, 3	
Task Force Recommendations, 4	
1 Introduction	7
Introduction, 7	
Risk Assessment, 7	
2 Disease Characterization: Hazard Identification	10
Introduction, 10	
Classification of Pathogenic Microorganisms, 16	
Viruses, 16	
Bacteria, 16	
Parasitic Protozoa, 17	
Other Parasites, 17	
Foodborne Infections, 17	
Foodborne Toxicoinfections, 19	
Foodborne Intoxications, 19	
3 Dose Response Assessment	21
Introduction, 21	
Components of the Digestive Tract, 21	
Introduction, 21	
The Digestive Tract, 21	
Defense Mechanisms, 22	
When Defenses Fail, 23	
Components of the Defense System and Attributes of Pathogens to Avoid Host Defenses, 23	
Stomach pH, 23	
The Intestinal Immune System, 24	
The Intestinal Flora, 24	
Bile Acids, 25	
Enzymes, 25	
High-Risk Populations, 25	
Doses Causing Infection and Illness, 26	
Predictions of Infection Based Upon Probability Models, 26	
Estimates of Doses Needed to Cause Illness, 29	
Severity of Illness, 29	
Concurrent Infections and Immunity, 30	
Estimates of Death Rates, 30	

4 Exposure Assessment	31
Introduction, 31	
Prevalence of Pathogens in Foods, 32	
Growth and Survival of Pathogens and Persistence or Destruction of Toxins in Foods, 35	
5 Risk Characterization: Estimated Numbers of Illnesses and Deaths	40
Sources of Data on Acute Foodborne Illnesses, 40	
CDC Foodborne Outbreak Data, 40	
CDC Laboratory-Based Surveillance Data, 41	
CDC Sentinel County Studies, 43	
Summary of Data Sources, 43	
Medical Data Indicating Infection by Foodborne Microorganisms, 43	
Expert Opinion, 44	
Risk Models, 47	
Limitations of Data Sources, 47	
Data on Chronic Foodborne Illnesses, 48	
Chronic Sequelae of Toxoplasmosis, 48	
Arthritis as a Sequela from Foodborne Pathogens, 49	
Hemolytic Uremic Syndrome as a Result of <i>Escherichia coli</i> O157:H7 Infection, 49	
Guillain-Barré Syndrome Preceded by <i>Campylobacter</i> Infections, 50	
Discussion and Conclusions, 51	
6 Risk Characterization: Economic Costs of Foodborne Diseases	53
Introduction, 53	
The Cost-of-Illness Method, 54	
Cost-of-Illness Estimates in the Literature, 54	
Willingness-to-Pay for "Safer" Food, 57	
Discussion, 60	
7 Prevention of Foodborne Illness	61
Introduction, 61	
Voluntary Food Industry Controls, 61	
Surveillance of Diseases, 61	
Surveillance of Food Establishment Workers, 63	
Surveillance of Feeds, Ingredients, and Foods, 65	
Surveillance of Physical Facilities and Equipment, 66	
Surveillance of Operations from Farm to Food Preparation, 66	
Training, 68	
Education, 68	
Regulatory Approaches, 69	
Future Trends and Food Control Opportunities, 70	
Appendix A: Acronyms and Symbols	73
Acronyms, 73	
Frequently Used Symbols, 73	
Appendix B: Glossary	74
Literature Cited	76
Index	84

Figures

- C.1 Abstract cover graph. Variation over time in vehicles for foodborne pathogens is caused by several factors, ii
- 2.1 A classification of foodborne diseases, 10
- 3.1 The organs and selected antimicrobial components or properties of the gastrointestinal tract, 22
- 3.2 Diagram of the layers of the small intestine, 22
- 3.3 A villus from the small intestine with adjacent crypt showing cellular diversity and perfusion, 23
- 3.4 The probability of developing infection based on exposure and infectivity of the pathogen ingested, 28
- 5.1 Sequential events in investigating a typical outbreak of foodborne illness, 41
- 5.2 Estimated cases and severity outcomes for *Escherichia coli* O157:H7 infections, 50
- 6.1 Foodborne disease, exposure, and types of costs, 53
- 7.1 Foodborne disease surveillance and intervention points, 64
- 7.2 Possible Hazard Analysis Critical Control Point (HACCP) goals, 67

Tables

- 1.1 Decades in which selected microbiological agents were recognized as causing foodborne disease, 7
- 2.1 Characteristics of foodborne organisms and toxins, 11
- 2.2 Certain foodborne infections and their complications, 18
- 3.1 Populations sensitive to foodborne disease in the United States, 25
- 3.2 Factors increasing the risk of foodborne infection or the severity of illness, 27
- 3.3 Risks of infection, morbidity, and mortality for consumption of viral-contaminated raw shellfish for a single exposure, 28
- 4.1 Selected illustrations of the prevalence of pathogens or potential pathogens in foods, 33
- 4.2 Factors enhancing shellfish-transmitted viral disease, 35
- 4.3 Survival and growth of pathogens or potential pathogens in foods, 37
- 5.1 Actual foodborne disease outbreaks, cases, and deaths, by etiologic agent reported to CDC, 42
- 5.2 Salmonellosis data from Centers for Disease Control (CDC) sources, number of annual cases, 43
- 5.3 Patients discharged from hospitals, by category of disease likely to have been foodborne, 45
- 5.4 Summary of sequential artifacts in *Salmonella* surveillance, 45
- 5.5 Best estimates of the annual cases and deaths for specific foodborne diseases in the United States, 46
- 5.6 Advantages of data sets, 48
- 5.7 Impairments caused by congenital toxoplasmosis in prospective studies, 48
- 6.1 Landefeld and Seskin's formula for estimating the value of a statistical life lost, 54
- 6.2 Cost estimates for medical expenses and value of lost productivity from intestinal infectious diseases, 55
- 6.3 Estimated annual costs of listeriosis illnesses and deaths, 55
- 6.4 Estimated annual incidences of *Escherichia coli* O157 H7 illness and costs, 56
- 6.5 Medical costs and productivity losses estimated for foodborne pathogens, 56
- 6.6 Total cost of foodborne disease in the United States, 58
- 7.1 Home, food service establishment, and food processing plant factors contributing to the occurrence of outbreaks of foodborne disease, 63
- 7.2 Data needed for estimating microbial health risks, 64

Foreword

Following a recommendation by the CAST National Concerns Committee, the CAST Board of Directors authorized preparation of a report addressing risks associated with foodborne pathogens.

Dr. Peggy F. Foegeding, professor, Department of Food Science, North Carolina State University, Raleigh, and Dr. Tanya Roberts, Economic Research Service, U.S. Department of Agriculture, served as coauthors of the task force. A highly qualified group of scientists was chosen to serve as authors and includes persons with expertise in economics, epidemiology, food safety, food science, infectious diseases, the law, medicine, microbiology, and public health.

The authors met and prepared an initial draft of the report. A meeting of a subcommittee of the task force and scientists at the Centers for Disease Control and Prevention in Atlanta, Georgia resulted in additional data being included in the report. A meeting of authors attending the Institute of Food Technologists' annual meeting in Atlanta, Georgia in June 1994 was held to discuss the final draft. All authors assisted in revising all drafts and reviewing the proofs. The CAST Executive and Editorial Review committees reviewed the final draft. The CAST staff provided editorial and structural suggestions and published the report. The chairs and authors are responsible for all scientific content in the report.

On behalf of CAST, we thank the authors who gave of their time and expertise to prepare this report as a contribution of the scientific community to public

understanding of the issues. Also, we thank the employers of the authors who made the time of these individuals available at no cost to CAST. The members of CAST deserve special recognition because the unrestricted contributions they have made in support of the work of CAST have financed the preparation and publication of this report.

This report is being distributed to members of Congress, the U.S. Department of Agriculture, the Food Safety Inspection Service, the Centers for Disease Control and Prevention, the Congressional Research Service, the Food and Drug Administration, the Environmental Protection Agency, the Agency for International Development, Office of Technology Assessment, Office of Management and Budget, media personnel, and to institutional members of CAST. Individual members of CAST may receive a complimentary copy upon request for a \$3.00 postage and handling charge. The report may be republished or reproduced in its entirety without permission. If copied in any manner, credit to the authors and CAST would be appreciated.

Justin R. Morris
President

Richard E. Stuckey
Executive Vice President

Kayleen A. Nijo
Scientific Editor

Interpretive Summary

The Council for Agricultural Science and Technology (CAST) created a task force to determine the state of knowledge about U.S. foodborne disease risks.

Task Force Findings

- A comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised. Although the microbial foodborne disease burden of the United States is not known with accuracy, estimates from the literature indicate and the general consensus of CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually.
- Although foods of animal origin most often are identified as the vehicles of foodborne disease outbreaks reported to the Centers for Disease Control and Prevention (CDC), a wide variety of foods are associated with foodborne illness.
- No agreed-upon method for setting food safety priorities exists.
- It is difficult to use available statistics, which are based on all routes (including nonfoodborne) of infection or intoxication, to identify the foodborne component of total human illness.
- Control methods affect specific pathogens and toxins differently; no one method will eliminate all pathogens and their toxins from the food chain. Pathogens or their toxins may be controlled by preventing their entry into the food, by reducing the amount present, or by destroying that which is present.
- Application of hazard analysis critical control point (HACCP) systems can reduce the likelihood of foodborne illness. The efficacy of a HACCP system depends on the rigor and consistency with which it is designed and implemented and the use of (a) critical control point(s) that will control pathogens.

Recommendations for Reducing Foodborne Illness

1. **We recommend that food safety policy be based on risk assessment** using all available data for acute and chronic foodborne disease.
2. **We recommend that the food safety information database be expanded** to provide more complete information on the incidence of foodborne disease by pathogen and by food.
3. Recognizing that advances in knowledge of foodborne disease prevention and control are essential to advancing food safety, **we recommend that vigorous fundamental and applied research efforts related to food safety be encouraged and supported.**
4. **We recommend that new rapid, reliable, sensitive, and economical methods continue to be developed** to allow fast and accurate detection of hazardous organisms and their toxins.
5. **We recommend that continued rigorous epidemiological studies be conducted** to assist in establishing the cause of illness and effect of the occurrence of a particular pathogen or toxin.
6. We acknowledge that both **dose response and minimum infective or intoxicating dose** are difficult types of data to accumulate yet **we recommend that, to the extent possible, these data and doses be determined or estimated.**
7. **We recommend that estimates of (a) numbers of acute illnesses, chronic illnesses, and deaths; (b) costs of foodborne diseases; (c) severity of illnesses; and (d) duration of chronic illnesses be improved.**
8. **We recommend that research be conducted on the mechanisms of chronic illnesses** with which foodborne pathogens are associated, so that appropriately targeted detection and control strategies can be developed.
9. **We recommend that research be conducted to identify foods likely to be associated with specific pathogens or toxins, and to estab-**

lish risk minimization controls. Whether new processing methods create an environmental niche for pathogens should be determined.

10. **We recommend that populations at high risk for opportunistic pathogens causing acute or chronic illnesses be identified and that special control programs be tailored to inform these populations of their high-risk status** so that they can protect themselves.
11. **We recommend that consumers be allowed choices in the types of food available** to them yet be made aware of their relative risk status, including their risks of acute as well as chronic illnesses.
12. **We recommend that federal food safety reg-**

ulations be modified to reflect that zero risk of foodborne illness is not possible.

13. **We recommend that food safety goals and priorities be set so that resources may be allocated and targeted appropriately.**
14. **We recommend that control practices be applied from food source to consumption,** including the incorporation of HACCP principles. New scientific advances should be incorporated into control practices.
15. Given that risk communication is critical because zero risk is impossible, **we recommend that the public be well educated regarding safe food handling and the relative and changing risk status of individuals.**

Summary

Charge to the Task Force

In 1983, the National Research Council (NRC) recommended that risk assessment procedures be applied to strengthen the scientific basis of risk decisions within the government. Risk assessment, risk management, and risk communication are the three components of risk analysis. In 1985, the NRC recommended that microbial pathogen risk assessment be the foundation for the nation's meat and poultry inspection system. In 1989, the Council for Agricultural Science and Technology (CAST) created a task force to determine the state of knowledge about U.S. foodborne disease risks. Recently several groups have emphasized the need for foodborne disease risk assessment, and improvements based on a risk assessment approach have been proposed (Bromley, 1993; Hathaway, 1994; U.S. General Accounting Office, 1992).

The CAST task force framed the issue by addressing the following questions:

- What types of human health risks are associated with microbial pathogens in food?
- What foods harbor these pathogens and are the causes of human disease?
- How many acute microbial foodborne illnesses and deaths occur annually?
- How many chronic human illnesses and deaths are caused by foodborne pathogens?
- What are the economic costs of these foodborne diseases annually?
- Are risk assessment databases adequate or are improvements needed to reduce uncertainty about the incidence of acute and chronic foodborne diseases?
- What preventive actions will reduce the incidence and severity of microbial foodborne disease?

Task Force Findings

1. A comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised.

- The Centers for Disease Control and Prevention's (CDC) foodborne surveillance system is limited by the data it receives from state departments of health and other sources and thus reports only a fraction of foodborne disease outbreaks.
- In 1994, the Council of State and Territorial Epidemiologists pointed out that final decisions regarding foodborne disease surveillance are made by each state and that 12 states have no surveillance staff assigned to monitor food related or waterborne pathogens; thus, outbreaks are unlikely to be reported from these states.
- The last systematic CDC study to estimate the actual incidence of foodborne bacterial, viral, and parasitic infections was conducted in 1983 and relied greatly on expert judgment (Bennett et al., 1987; Voelker, 1994). A new study is needed urgently.
- Trends in the CDC's reported foodborne outbreaks may not reflect changes in actual cases accurately. New pathogens always are underreported because testing procedures are nonstandardized or have not been developed, or because doctors tend to request tests for familiar pathogens. For *Campylobacter jejuni*, the causes of reported outbreak cases and of sporadic cases not reported but detected by special investigations differ. Similar differences may exist for other pathogens.
- For some illnesses, it may take thousands of cases for an outbreak causing diarrheal illness randomly in a large urban area to be detected by public health authorities (Berkelman et al., 1994).
- Any assessment based solely on currently known pathogens and disease syndromes likely is incomplete. New etiologies continue to be added as the science base expands, but nearly half of the recorded outbreaks and cases still are of unknown etiology (Bean et al., 1990a, 1990b).

Although the microbial foodborne disease burden of the United States is not known with accuracy, estimates from the literature indicate and the general consensus of CAST task force members is that cases likely range from 6.5 million to 33 million annually and that deaths may be as high as 9,000 annually (the CDC estimates that there are 9,000 microbial foodborne deaths annually).

2. Although foods of animal origin most often are identified as the vehicles of foodborne disease outbreaks reported to the CDC, a wide variety of foods are associated with foodborne illness (Bean et al., 1990a, 1990b).
3. No agreed-upon method for setting food safety priorities exists. The U.S. Health and Human Service's *Healthy People 2000* report used, without a clear definition, both case number and severity to set targets for *Campylobacter jejuni*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella enteritidis* (U.S. Department of Health and Human Services, 1991).
4. It is difficult to use available statistics, which are based on all routes (including nonfoodborne) of infection or intoxication, to identify the foodborne component of total human illness.
5. Pathogens and their toxins can enter the food chain at any point from the farm to the kitchen. Pathogens or toxins may be present on raw foodstuffs or may be introduced into the food by contamination in the postharvest environment, e.g., by processing plant workers or by foodhandlers. The ability to survive, to grow, and to produce toxin and the persistence of active toxins are consequences of organism, environment, and treatment process. Thus, methods to prevent or to control pathogens differ and may involve excluding contaminated feed and food ingredients, practicing good sanitation, refrigerating, cooking, or irradiating. Control methods affect specific pathogens and toxins differently; no one method will eliminate all pathogens and their toxins from the food chain. Pathogens or their toxins may be controlled by preventing their entry into the food, by reducing the amount present, or by destroying that which is present.
6. Application of hazard analysis critical control point (HACCP) systems can reduce the likelihood of foodborne illness. Control systems must recognize the diversity and the variability of pathogens, the vagaries of detection, and the wide range of control options. The cost and efficacy of HACCP systems differ considerably, and creative

Foodborne Pathogens: Risks and Consequences

solutions may be pathogen-specific. In each instance, the efficacy of a HACCP system depends on the rigor and consistency with which it is designed and implemented and the use of (a) critical control point(s) that will control pathogens.

Task Force Recommendations

The task force acknowledges that zero risk of foodborne illness is neither possible nor practical. We offer the following recommendations for reducing foodborne illness.

1. **We recommend that food safety policy be based on risk assessment** using all available data for acute and chronic foodborne disease.
2. **We recommend that the food safety information database be expanded** to provide more complete information on the incidence of foodborne disease by pathogen and by food risk assessment use. The database should be accessible through a computer network to all potential users (public health officials, regulatory authorities, food companies, food safety scientists, and others). The CDC should take the lead in creating the new database with input from the Food Safety Inspection Service (FSIS); the U.S. Food and Drug Administration (FDA); state departments of health; and other individuals or organizations, e.g., the database should include consumer illness complaints and survey data. This integrated database would allow identification of the points at which pathogens occur in the food chain and would facilitate identification of pathogen control points, estimation of control option costs, and tracking of intervention success in terms of reduced human illness and death.
3. Recognizing that advances in knowledge of foodborne disease prevention and control are essential to advancing food safety, **we recommend that vigorous fundamental and applied research efforts related to food safety be encouraged and supported.** Research on the biology and the ecology of pathogens is especially important in areas such as microbial ecology of pathogenic bacteria and viruses; genetic transfer of virulence determinants; mechanisms of virulence; potential of growth conditions to enhance virulence; sensitivities of pathogens and toxins to control procedures; activities and responses of organisms in natural environments, e.g., biofilms in processing facilities; and applications of current technologies for tracking organisms in the

Summary

5

environment and in epidemiological investigations.

4. **We recommend that new rapid, reliable, sensitive, and economical methods continue to be developed to allow fast and accurate detection of hazardous organisms and their toxins.** This objective is especially important for detection of viruses in food, environmental, and fecal samples because viral detection methods are inadequate.
5. We acknowledge that epidemiological studies to link incidence of a foodborne pathogen to illness will be increasingly important as detection method sensitivity for pathogens or for their toxins increases. Therefore, **we recommend continued rigorous epidemiological studies to assist in establishing cause of illness and effect of the occurrence of a particular pathogen or toxin.**
6. We acknowledge that both **dose response and minimum infective or intoxicating dose** are difficult types of data to accumulate (because the use of human volunteers is unacceptable) yet **we recommend that, to the extent possible, these data and doses be determined or estimates be improved** using data from well-documented outbreaks.
7. **We recommend that estimates of (a) numbers of acute illnesses, chronic illnesses, and deaths; (b) costs of foodborne diseases; (c) severity of illnesses; and (d) duration of chronic illnesses be improved.**
8. **We recommend that research be conducted on the mechanisms of chronic illnesses with which foodborne pathogens are associated, so that appropriately targeted detection and control strategies can be developed.**
9. **We recommend that research be conducted to identify foods likely to be associated with specific pathogens or toxins, i.e., high-risk foods such as raw foods of animal origin, and to establish risk minimization controls.** Whether new processing methods create an environmental niche for pathogens should be determined.
10. **We recommend that populations at high risk for opportunistic pathogens causing acute or chronic illnesses be identified and that special control programs be tailored to inform these populations of their high-risk status so that they can protect themselves.** An interactive computer database could be established on Internet to list foods likely to harbor the pathogen of interest, to improve understanding of the safest handling and preparation procedures for specific foods, and to help high-risk populations select optimal food/safety combinations. These populations may include persons with low stomach acidity, high-iron blood level, or diabetes; alcoholics; children; pregnant women; adults over 50 or 60; those with organ transplants, cancer, or acquired immunodeficiency disease syndrome (AIDS); or others. Educational strategies must acknowledge that the risk status of individuals is not constant.
11. **We recommend that consumers be allowed choices in the types of food available to them yet be made aware of their relative risk status, including their risks of acute as well as chronic illnesses.** It should not be required that all foods be safe for consumption by high-risk consumers; this would greatly limit food choices, e.g., to canned or irradiated food, excluding fresh meat, poultry, and seafood. Special federal programs could be established to certify the safety of specific operations to produce foods for high-risk individuals; these foods probably would be priced higher.
12. **We recommend that federal food safety regulations and policies be modified to reflect that zero risk of foodborne illness is not possible.** This change will allow honest and effective risk management.
13. **We recommend that food safety goals and priorities be set so that resources may be allocated and targeted appropriately.** Public discussion and understanding of the costs and effectiveness of control measures will be requisite.
14. **We recommend that control practices be applied from food source to consumption,** including the incorporation of HACCP principles from the farm or other source through consumption. The HACCP systems provide a systematic process-control approach focusing on food safety. Development of new procedures to control foodborne illness agents, as well as understanding of existing control steps and control procedure costs, should be encouraged so that proper and effective application is ensured. Controls for each food pathogen combination should be evaluated separately. New scientific advances should be incorporated into control practices.
15. Given that risk communication is critical because zero risk is impossible, **we recommend that the public be well educated regarding safe food handling and the relative and changing risk**

status of individuals. Education is essential if consumers are to protect their own health and to recognize the political and regulatory complexities of the issue so that they can participate in setting food safety goals. From grades K–12, science education should be strong and education concerning the hazards of foodborne diseases, their causes, and their means of prevention

should be integrated into health and science curricula. Health agency personnel and university outreach programs should inform consumers about populations at risk for foodborne illness, the relative safety of various food choices, safe food handling procedures, appropriate control strategies, and the relative effectiveness of controls.

APPENDIX 6.—ADDITIONAL STATEMENTS SUBMITTED FOR THE JUNE 16, 1994, HEARING RECORD

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FOR FOOD & HEALTH POLICY

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FOR IMMEDIATE RELEASE
June 16, 1994

Statement of Mark S. Epstein Executive Director, Public Voice for Food and Health Policy on Poultry and the "Fresh" Label

American consumers expect the federal government to work on their behalf to ensure that the information they receive on product labels is accurate and not misleading. This explains the overwhelming consumer support for the Food Safety and Inspection Service's and Food and Drug Administration's efforts to overhaul food labeling and to mandate safe handling labels for meat and poultry.

FSIS's current definition of "fresh" as it applies to poultry does a disservice to consumers. Allowing poultry that has been frozen and then thawed to be labeled as fresh is deceptive and misleading.

Public Voice calls on FSIS to change its definition of fresh to reflect consumers' temperature and time concerns. At present, the best definition of fresh has been FSIS's 1988 determination of poultry kept above 26 degrees Fahrenheit. Poultry that has been frozen and then thawed should be clearly identified as "previously frozen."

In general, consumers believe that fresh poultry has been recently slaughtered and has never been frozen. They have demonstrated a willingness to pay a premium price for this product. If a product has been previously frozen, it will not merit this higher price in the eyes of many consumers. It is critical that FSIS give consumers the information they need to make a fully informed choice.

Mandating such a definition for fresh also would be consistent with the meaningful new definitions that FSIS has developed for nutrition descriptors such as "light" and "healthy." This consistency would only build consumers' trust in the agency and in the candor of today's food marketplace.

As consumers search for lower fat food products, the poultry market should continue to thrive. Differentiating between "fresh," "previously frozen" and "frozen" poultry would allow processors to compete fairly in this growing marketplace without misleading consumers. It would also provide consumers with two more affordable choices if they did not want to pay the premium for "fresh" poultry. By permitting the current labeling to persist, FSIS restricts the forces of competition, deprives consumers of more affordable options and undermines consumers' right to make informed purchases.

Public Voice was one of the leading consumer groups active in the development of the Nutrition Labeling and Education Act. Public Voice has presented testimony, commented on agency regulations and published a number of research reports on issues such as meat and poultry labeling, standards of identity and consumer attitudes toward food labeling claims such as "lite."

PETE WILSON
GOVERNOR



State and
Consumer Services Agency

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Building Standards Commission
Consumer Affairs
Fair Employment & Housing
Fire Marshal
Franchise Tax Board
General Services
Museum of Science & Industry
Personnel Board
Public Employees' Retirement System
Teachers' Retirement System
Veterans Affairs

Written Testimony by Joanne Corday Kozberg
Secretary of State and Consumer Services Agency

Government Operations Subcommittees of
-Human Resources and Intergovernmental Relations-
-Information, Justice, Transportation and Agriculture-
U.S. House of Representatives--Washington, DC
Room 2154 Rayburn
June 16, 1994--9:30 am.

As California's Secretary of State and Consumer Services Agency, I wish to submit testimony on the "fresh" poultry issue.

One of this Agency's chief responsibilities is to protect the public from deceptive and fraudulent business practice. In a state as large as California, with over 30 million consumers, this is a tremendous task. It is our mission to educate and inform consumers in an effort to equip them to make informed decisions.

I am especially anxious to underscore the nature of this fresh labeling issue from a consumer protection standpoint, not solely an agricultural perspective. California has always been a leader in consumer protection issues, and the fresh poultry controversy is about consumers' right to know.

Consumers want to be informed and careful about what they purchase and eat. When they buy something labeled "fresh", they believe it really is fresh. Consumers buy fresh food under the assumption that it has never been frozen and have no idea they're being overcharged or are buying a previously frozen product. Considering that fresh chicken costs more than frozen chicken, by \$.40 per pound or more, the economic consequences of this fraud are substantial.

It has been determined that 25 degrees Fahrenheit is the natural temperature at which chicken freezes solid at the core and last year the California Legislature and Governor Wilson unanimously approved legislation reflecting that reality. The California law does not limit the sale of poultry from outside California, nor does it even require that the poultry be labeled "frozen." The California law merely prohibits the labeling of poultry frozen below 26 degrees Fahrenheit as "fresh."

The USDA filed a brief against California's law and a Federal judge blocked enforcement of California's law based on preemption by the existing Federal standard. The Federal standard, which allows the chicken to go as low as 1 degree and still be labeled fresh, is misleading the consumer. If a state cannot legally protect its consumers from this type of fraud, then a revised Federal rule is essential. Doesn't the Federal government have an obligation to the consumer?

As Harry Snyder, Director of the West Coast office of the Consumer's Union aptly stated in the Washington Post, "When people buy something labeled 'fresh,' they don't expect to be able to bowl with it."

The California law is about protection--not protectionism. The chicken consuming market in California is the largest in the country and there is ample demand for both out-of-state and in-state suppliers. We are not trying to keep anyone out--we just want to make sure they tell the truth about their products. California's law is not designed to suppress competition as national producers might suggest--rather the law is to promote accurate information for California's customers when they go to the store to choose among the competition.

We believe the Federal government would do well to follow suit and return to the rule it adopted in 1988, when USDA's Food Safety and Inspection Service issued a policy raising the fresh poultry labeling standard from 1 to 26 degrees Fahrenheit (Memo 022B). Unfortunately, that policy was overturned.

If we must depend on USDA to regulate in this area, truth in labeling must be a priority. It is common sense that a chicken hard enough to bang on the table like a rock is not fresh. It may be tasty; it may be a good buy; but it just isn't fresh!

- 4 -

In many cases, a chicken is frozen in the Southeast, shipped out West, and thawed before it is sold in the store as "fresh." The consumer then buys this supposedly "fresh" product and brings it home to refreeze. Now the chicken is frozen not only once but twice. I should think consumers would want to know if they are refreezing any meat product, including poultry, that has previously been thawed due to potential health risks, which may be posed by repeated thawing and refreezing.

Regional producers who market truly fresh poultry will rightfully continue their quest to raise the standard to 26 degrees. Unfortunately, their voices will continue to be challenged by the powerful national lobby who want to preserve the status quo.

We urge you to review the Federal standard closely. We think you will find that it does not meet today's consumer expectations for truth in labeling. We understand Secretary Espy has committed to review the Federal policy. Please do not permit this public process to be delayed, or worse, be buried in bureaucracy. Thank you.

#

APPENDIX 7.—ADDITIONAL MATERIAL FOR THE JUNE 16, 1994, HEARING RECORD

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRTH CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

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June 14, 1994

MEMORANDUM

TO: Members of the Subcommittees on Human Resources and
Intergovernmental Relations and Information, Justice, Transportation and
Agriculture

FROM: Edolphus Towns and Gary A. Condit, Chairmen

RE: Joint Hearing: "Fresh vs. Frozen Chickens and Other Issues Involving USDA's
Regulation of Poultry Products," **Thursday, June 16, 1994**, at 9:30 a.m., 2154
RHOB

I. INTRODUCTION

When is a chicken "fresh" and when is it "frozen?" Although the question refers to honesty in labeling, the issues underlying the question involve industry influence over the regulators, federal preemption of state laws, the promulgation of policy guidelines, and the regulation of poultry products in general.

II. BACKGROUND

The U.S. Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) oversees the slaughter and processing of poultry sold in interstate commerce and inspects imported poultry products to ensure that they are safe, wholesome, and properly labeled. FSIS carries out a "continuous inspection" program at poultry slaughterhouses, which by law may operate only when one of FSIS's field inspectors is on duty. FSIS inspectors also monitor processing plant operations, such as deboning, to ensure that plants are sanitary and adhere to approved procedures. In addition, FSIS must also approve all labels for poultry products before the products can be marketed to ensure that they accurately represent the product.

As of April 13, 1994, there were 6,556 federally inspected meat and poultry plants. Of these, 456 plants (7 percent) were approved for poultry inspection only and 3,916 plants (60 percent) were approved for both meat and poultry inspection. In fiscal year 1993, FSIS devoted over 9,000 staff years and about \$660 million to oversee meat and poultry plants. FSIS inspects roughly 6.5 billion chickens and almost 3 million turkeys each year.

III. RELEVANT LAWS

The Poultry Products Inspection Act, as amended, (PPIA) (21 U.S.C. 451 et seq.)

II. OBJECTIVES OF THE HEARING

This hearing will examine USDA's policy for labeling "fresh" vs. "frozen" poultry and whether the current policy was unduly influenced by certain segments of the poultry industry. In view of the Human Resources and Intergovernmental Relations Subcommittee's previous hearings on the safety of meat and poultry (November 4 and 19, 1993), as well as recent allegations that USDA has been lenient in regulating poultry products, we have asked USDA to discuss its regulation of poultry products in general, including, but not necessarily limited to, (1) USDA's announced poultry enhancement program; (2) the results of Research Triangle Institute's study entitled, Comparison of USDA Meat and Poultry Regulations; and (3) the status of all pathogen reduction activities involving the safety and quality of poultry products, including the former Assistant Secretary's pledge to the subcommittee to reevaluate the meaning and use of the USDA inspection seal.

The USDA Office of Inspector General has investigated whether the Secretary of Agriculture committed any impropriety involving Tysons Foods Inc., a major poultry producer, and has referred the case to the Department of Justice. Because this matter is an open criminal investigation and before the Department of Justice, these allegations are not yet ripe for review at this hearing. However, at the request of the minority members, we have requested that the USDA Inspector General testify on his investigation at the hearing.

IV. WITNESSES

Richard Rominger, Deputy Secretary of Agriculture
 Henry J. Voss, Director, California Department of Food and Agriculture
 Wolfgang Puck, Chef
 Dr. Lester Crawford, Executive Director, American Association of Veterinary
 Medical Colleges
 Linda S. Golodner, President, National Consumers League
 Rodney Leonard, Executive Director, Community Nutrition Institute
 Bill Mattos, President, California Poultry Industry Federation
 Dr. Kenneth N. May, Technical Advisor, National Broiler Council
 Larry Fanella, Chairman, National Turkey Federation

VI. MAJOR ISSUES

A. USDA'S REGULATIONS DO NOT DEFINE "FRESH"

Neither the Poultry Products Inspection Act (PPIA), as amended, nor USDA's regulations defines "fresh" poultry or requires labeling of poultry as "fresh." However, USDA's regulations define the term "frozen" and limit the use of the term on labels. According to 9 C.F.R. Sec. 381.66(f)(2), poultry is frozen when the internal temperature reaches 0° Fahrenheit (F) within 72 hours from the time entering the freezer. According to 9 C.F.R. Sec. 381.129(b)(3), poultry may be labeled "frozen" only if it meets the definition in 9 C.F.R. Sec. 381.66(f)(2). USDA regulations also specify general chilling requirements: "All poultry that is slaughtered and eviscerated in the official establishment shall be chilled immediately after processing so that the internal temperature is reduced to 40°F or less,...unless such poultry is to be frozen or cooked immediately at the official establishment."

On January 11, 1989, USDA's Food Safety Inspection Service (FSIS) issued Policy Memo 022C to set forth its informal interpretation of its regulations for when "fresh" may be used on approved labeling of meat and poultry products. Policy Memo 022C provides, in part, "The word 'fresh' may not be used in conjunction with the product name of: (3) Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit." Thus, according to Policy Memo 022C, USDA's regulations permit a poultry product to be labeled "fresh" if it has been stored at temperatures above 0°F and at or below 40°F. In other words, poultry may be labeled as "fresh" if it doesn't meet the definition of "frozen."

B. THE POLICY MEMO CONTROVERSY

The development and issuance of Policy Memo 022C is controversial. On the basis of internal USDA documents obtained by the subcommittees and interviews with key USDA officials responsible for the Policy Memo, it appears USDA/FSIS issued Policy Memo 022C only as a result of industry pressure by groups such as the National Broiler Council. Policy Memo 022C superseded Policy Memo 022B which provided for a much higher temperature threshold to define 'fresh' poultry for labeling purposes.

According to Policy Memo 022B, which FSIS issued on July 11, 1988, "The word 'fresh' may not be used in conjunction with the product name of: (3) Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location)." Thus, according to Policy Memo 022B, the term 'fresh' could only be used on labels of poultry products that had not been chilled to a temperature of 26°F or less. According to information obtained by the subcommittees, USDA established the temperature threshold at 26°F based on a review of the scientific literature, USDA poultry grading guidance, and contacts with academia. According to Dr. Lester Crawford, former administrator of FSIS

at the time, FSIS had determined scientifically that 26°F was the best dividing line between fresh and frozen poultry. In fact, an internal 1988 USDA staff memo stated, "Therefore, the 26°F temperature appears to be very soundly based and is, in fact, another very generous accommodation towards the industries needs, both from a safety and esthetics perspective."¹ (USDA developed Policy Memo 022B partly in response to a request from Purdue Farms to review USDA's position on the use of frozen poultry in further processed fresh poultry products.)

Segments of the poultry industry that slaughter and ship poultry products to distance places in the country, such as Holly Farms (now owned by Tysons Foods), loudly complained to USDA about Policy Memo 022B. For example, Dr. Crawford has stated that he and former Secretary of Agriculture Richard Lyng met twice with certain members of the National Broiler Council (NBC), including Holly Farms and Marshall Durbin, on revising Policy Memo 022B. According to Dr. Crawford,

Secretary Lyng instructed me to meet with the members of the NBC to resolve the issue. Secretary Lyng told me to work with the NBC members to develop an acceptable accommodation. I met with certain members of the NBC. I was told that the vast majority of the NBC members wanted Policy Memo 022B abrogated. The NBC was unwilling to accept any compromise position. The NBC's position was that Policy Memo 022B be rescinded. During the consideration of Policy Memo 022B and 022C, no consumers or state officials had input into these policy decisions. Given the position of the NBC, I reluctantly rescinded Policy Memo 022B. On January 11, 1989, the FSIS issued Policy Memo 022C, which superseded Policy Memo 022B.²

According to information obtained by the subcommittees, between July 11, 1988 and January 11, 1989, FSIS staff worked on a revision to Policy Memo 022B that provided for a temperature range of 28 to 24°F to distinguish "fresh" vs. "frozen" poultry. Ultimately, however, FSIS did not adopt the temperature range and issued Policy Memo 022C. The rationale for Policy Memo 022C stated, in part,

This decision is predicated on the belief that it is not practical under existing marketing strategies and distribution patterns, to define 'fresh' in terms of internal temperature beyond the scope of the current regulations, nor is it practical to define consumer expectations for poultry products labeled as 'fresh.' The consumer is the best judge of preference in chilling temperatures for unprocessed poultry products labeled as 'fresh,' and therefore the marketplace is best suited for making this type of decision.

However, in his declaration, Dr. Crawford stated:

I still believe that the conclusions stated in Policy Memo 022B were and

are correct. I also continue to believe that it is misleading to label poultry that has been frozen to 26 degrees Fahrenheit or below as fresh because such poultry is clearly frozen. The change from 26 to zero degrees Fahrenheit was made as a political compromise.³

In an interview with staff from the subcommittees, Dr. Crawford stated that he rescinded Policy Memo 022B because the poultry industry could not reach agreement on a compromise and there was increasing concern about the safety of poultry products at that time. Dr. Crawford also stated that he was concerned about whether changing the temperature of poultry products in transport would increase food borne illness associated with poultry. However, Dr. Crawford admitted that FSIS did not have good data on this safety concern and his declaration does not mention safety as a factor in revising the policy memo.

C. USDA IS REEVALUATING ITS POLICY ON "FRESH" POULTRY

USDA officials have expressed dissatisfaction with the current policy on "fresh" poultry. According to a January 7, 1994, memo from John McCutcheon, Deputy Administrator, Regulatory Programs, FSIS, to H. Russell Cross, former administrator of FSIS, "Many on the staff feel that the USDA position has not been and is not now reasonable and that a higher temperature for 'fresh' products is more in line with consumer expectations and yet will not create microbial problems."⁴ Furthermore, according to a January 26, 1994, memo from Patricia Jensen, Acting Assistant Secretary for Marketing and Inspection Services to the Deputy Secretary, "This policy has been in existence for many years and has been embarrassing to the Department on a number of occasions."⁵

Subsequently, on February 10, 1994, USDA announced that Agriculture Secretary Mike Espy had directed USDA to reexamine its policy for use of the term "fresh" on poultry product labels. According to information obtained by the subcommittees, USDA is in the process of reevaluating its policy, including conducting several scientific analyses of freezing and microbial activity and planning options for obtaining consumer input on what is "fresh." The Deputy Secretary will provide information on these activities in his testimony.

D. THE CALIFORNIA POULTRY LAW

On September 23, 1993, the State of California enacted a law aimed at controlling the usage of the term "fresh" on poultry products. The law was due to take effect on January 1, 1994. The statute prohibited wholesalers from using the term "fresh" on any poultry product that has been handled at a temperature of 25 degrees F or lower, or has been stored at that temperature for more than 24 hours.

In response to the California law, the National Broilers Council, the American

Meat Institute and the Arkansas Poultry Federation, filed suit in federal court and were able to gain an injunction in December, 1993 that stopped the law from taking effect. On April 8, 1994, United States District Judge David F. Levi issued an opinion that permanently enjoined the State of California from enforcing the law. Levi's opinion was based upon his interpretation of the PPIA, (21 U.S.C. §§ 451-470). Levi wrote that provisions in the PPIA prevented non-federal entities from passing laws that would usurp its authority:

Congress enacted the PPIA in 1957 "to provide for the inspection of poultry and poultry products and otherwise regulate the processing and distribution of such articles...to prevent the movement or sale in interstate or foreign commerce of, or the burdening of such commerce by, poultry products which are adulterated or misbranded." (21 U.S.C. § 452)

The PPIA contains an express pre-emption provision in a section entitled "Non-Federal jurisdiction of Federally regulated matters..." 21 U.S.C. §467e. Section 467e expressly pre-empts labeling requirements that are "in addition to, or different than" those made under the PPIA.

Levi's decision was appealed on April 15, 1994 by the California Department of Food and Agriculture in the U.S. Circuit Court of Appeals, 9th Circuit, San Francisco. The state also requested a stay of the district court judgement which, if granted, would allow the law to be enforced for the first time.

E. OTHER POULTRY RELATED ISSUES

In November, 1993, the Human Resources and Intergovernmental Relations Subcommittee began a series of hearings on the Vice President's proposal to reinvent federal food safety efforts by transferring responsibility for meat and poultry regulation from FSIS/USDA to the Food and Drug Administration. Two days of hearings on USDA's meat and poultry program revealed that USDA's inspection program is obsolete, misleading, and incapable of protecting the public from harmful microbial contamination--the primary cause of food-borne illness. The subcommittee learned that bacteria that make people sick easily escape the USDA's current sensory inspections because inspectors cannot see, feel, or smell microbial contamination. Several subcommittee members questioned whether the seal of wholesomeness that USDA stamps on every inspected piece of poultry was, in fact, misleading to consumers because of the potential for microbial contamination. During the subcommittee's hearing on November 19, 1993, former Assistant Secretary Eugene Branstool agreed to reconsider the meaning and use of this seal.

The subcommittee's hearings also revealed that despite being on notice for almost two decades, the USDA had failed to fix the fatal flaws in its inspection program. The National Academy of Sciences, the General Accounting Office, and many others have

repeatedly urged USDA to replace its obsolete inspection program with a scientific, risk-based system to protect public health. Yet witness after witness testified about USDA's pattern of failure to act. Many witnesses testified that the USDA's primary mission to promote agriculture overshadows its responsibilities to protect consumers and thwarts needed change. On May 25, 1994, GAO testified before the subcommittee that USDA has conflicting interests that undermine public confidence in the federal government's ability to ensure a safe food supply. Recent allegations of USDA leniency toward the poultry industry and influence over key USDA officials raise anew the troubling appearance of an institutional conflict of interest, which undermines consumer health and confidence.

This hearing will provide an opportunity to update the subcommittee on the progress USDA is making to reform its poultry inspection program and the need to remove the inspection program from USDA because of an actual or perceived conflict of interest inherent in that department's mission. For example, in May, 1993, Secretary Espy announced that USDA would present a package of legislative proposals to strengthen meat and poultry safety, but the department has not yet put forward its legislative proposals. Similarly, on March 9, 1994, USDA announced that it intended to publish a proposal to improve the poultry inspection system, called the "poultry enhancement program." However, USDA has not yet published any proposed rules.

VII. ENDNOTES

1.Memorandum from Ashland Clemons, Acting Director, Standards and Labeling Division, Technical Services, to Margaret O'K. Glavin, Acting Assistant Deputy Administrator, Technical Services, re: "Policy Memo on 'Fresh' Labeling," Oct. 12, 1988, p. 2.

2.Declaration of Dr. Lester Crawford, re: National Broiler Council, et al. v. Voss, Feb. 24, 1994, pp. 4-5. Note: Dr. Crawford was compensated for his declaration by either the defendant or the intervenor (California Poultry Industry Federation).

3.Crawford at p.5.

4.Memorandum from John W. McCutcheon, Deputy Administrator, Regulatory Programs, to H. Russell Cross, Administrator, re: "California 'Fresh' Law," Jan. 7, 1994.

5.Informational Memorandum for the Deputy Secretary from Patricia Jensen, Acting Assistant Secretary, Marketing and Inspection Services, re: "The Department's Position on the Definition of 'Fresh' Poultry," Jan. 26, 1994, p. 1.

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio

Bernard Sanders, Vermont
Independent

Majority (202) 225-2548
FAX (202) 225-2382
Minority (202) 225-2738

June 23, 1994

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

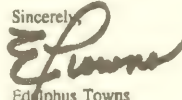
Dear Mr. Secretary:

As you are aware, in the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations jointly conducted a hearing on June 16, 1994, on the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. During the hearing, Representative John Mica, a member of the Human Resources and Intergovernmental Relations Subcommittee, requested that USDA provide documentation of contacts between USDA administrators and Tyson Foods, Inc.

In furtherance of this request, the subcommittee would appreciate receiving the following information and documents by C.O.B., Friday, July 1, 1994: Copies of all written correspondence and a list of all meetings, telephone calls and other communications between USDA Administrators, including Mr. Richard Rominger, Deputy Secretary, and Tyson Foods, Inc., and the Arkansas Poultry Federation from January 20, 1992 through June 1, 1994, especially any communications between September 23, 1993 and April 1, 1994.

Thank you in advance for your cooperation. Please contact Bill Layden of the subcommittee staff at (202) 225-2548 if you have any questions.

Sincerely,



Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

cc: The Honorable Steven Schiff
(Ranking Minority Member)



United States
Department of
Agriculture

Office of
Communications

Washington, D.C.
20250-1300

June 30, 1994

**MEMORANDUM FOR CHARLIE RAWLS, EXECUTIVE ASSISTANT
TO THE DEPUTY SECRETARY, OFFICE OF THE SECRETARY**

FROM: Milton Sloane 
Freedom of Information Act Coordinator
Office of Communications

SUBJECT: Letter from Congressman Edolphus Towns

AMS, APHIS, and ARS (the Agricultural Marketing Service, Animal and Plant Health Inspection Service, and the Agricultural Research Service, respectively) have informed me that they have no documents responsive to Congressman Towns' request regarding Tyson Foods, Inc., and the Arkansas Poultry Federation. Marty Rookard of Pat Jensen's office is to notify you directly of the outcome of the search for records in that area. If there is any additional information you wish, please let us know.

ITINERARY - DEPUTY SECRETARY RICHARD ROMINGER
 ARKANSAS ELECTRIC COOPERATIVE CORPORATION
 EUREKA SPRINGS, ARKANSAS
 AUGUST 1-2, 1993

Sunday, August 1

1:00 pm	Private auto - home to airport	_____
	Taxi/subway - home to airport (Charlie will meet you at the airport)	mileage
1:43 pm	Lv. National via AA 1533 (Seat 7F (Charlie 21A)	
2:31 pm	Ar. Nashville, Tennessee	
3:10 pm	Lv. Nashville via AA 3611 (Seat 10C)	
5:02 pm	Ar. Fayetteville Met by Ron Ralph OIG Agent	
	Drive to Eureka Springs, approx. 37 miles	
	HOTEL: Inn of the Ozarks Highway 62	
	CONF. # 0781	
	PHONE: 501-253-9768	
	FAX: 501-253-9768 (same)	
8:00	DINNER - Plaza Hotel Carl Willock, Pres. Arkansas Electric Dennis Robertson, VP, Arkansas Electric Steve Williams, Lawyer (Maybe a few more)	

Monday, August 2

7:00 am to 8:30 am	Buffet Breakfast Convention Center
9:00 am	General Session Begins Master of Ceremonies, David Sain , Vice President Systems Services/AECI/AECC
	Welcome to Eureka Springs! The Honorable Randy Wolfinbarger, Mayor of Eureka Springs

Competitiveness and Fair Treatment:
 Watchwords for the 1990's
 Carl S. Whitlock, President, CEO, AECE/AECC

ADDRESS THE DIRECTORS' SUMMER MEETING

10:30 am Depart Eureka Springs with OIG Agent driving and Dr. Milo J. Shult, Vice President for Agriculture of the University of Arkansas System and Director of Extension will join you at the meeting and accompany you throughout the tour. CONTACT: Dr. Milo J. Shult, 501-575-2251

11:30 pm LUNCH at Springdale with Poultry Industry leaders
 to John Tyson, Tyson Poultry, Inc. (John is the son of Don Tyson,
 1:30 pm President of Tyson Poultry). Accompanying him will be a number of Executive Staff (Vice Presidents) of Tyson Poultry, Inc.
 Dr. Dan Ferritor, Chancellor, University of Arkansas - Fayetteville
 Dr. James Denton, Head of the Poultry Center of Excellence, University of Arkansas
 Dr. Milo Shult, Vice President for Agriculture, University of Arkansas System

Tyson's Corporate Office - 504-756-4000

1:45 pm Tour of Poultry Center of Excellence
 to
 2:30 pm

2:30 pm Review of Hydrological Unit with ASCS, SCS and Extension

Mr. Wayne Perryman, Director State ASCS
 Mr. Ronnie Murphy, State Conservationist, SCS
 Dr. Shult, Director of Extension

Briefing will be conducted by three county based staff. Names will be provided on site.

4:40 pm Lv. Fayetteville via AA 3999 (Seat 11B)
 (Charlie 10B)

6:26 pm Ar. Nashville
 7:20 pm Lv. Nashville via AA 1334 (Seat 27D)
 (Charlie 30D)

9:56 pm Ar. National

Taxi/subway - airport to home _____



United States
Department of
Agriculture


Agricultural
Stabilization and
Conservation Service

P.O. Box 2415
Washington D.C.
20013-2415

SUBJECT: Documentation of Contacts Between USDA Administrators and Tyson
Foods, Inc.

TO : Eugene Moos
Under Secretary for International Affairs and Commodity Programs

In response to your memorandum of June 28, 1994, the Agricultural Stabilization and Conservation Service (ASCS) submits a negative report. However, ASCS does perform service functions on behalf of the Agricultural Marketing Service (AMS). The Kansas City Commodity Office (KCCO), as part of its operational responsibility, services AMS's poultry contracts. Therefore, KCCO would have had ongoing telephone conversations with Tyson Foods regarding shipments under AMS contracts. In addition, KCCO also makes payments to Tyson Foods for the delivery of commodities.


Grant Buntrock
Administrator



AN EQUAL OPPORTUNITY EMPLOYER



United States
Department of
Agriculture

Foreign
Agricultural
Service

Washington, D.C.
20250

JUN 29 1994

INFORMATIONAL MEMORANDUM FOR THE UNDER SECRETARY

FROM: Richard B. Schroeder
Acting Administrator *[Signature]*

SUBJECT: Contact with Tyson Foods, Inc.

— REF: Kathy Blythe Memo of June 28, 1994

The Foreign Agricultural Service has no documents related to communication between the Administrator's Office or the Deputy Secretary's Office and Tyson Foods, Inc., nor the Arkansas Poultry Federation.



United States
Department of
Agriculture

Farmers
Home
Administration

Washington
D.C.
20250

JUN 28 1994

SUBJECT: Contacts Between USDA Administrator
Tyson Foods, Inc. and Arkansas
Poultry Federation

TO: Kathy Blythe, IACB

As requested, per memorandum dated June 28, 1994, no contact
has been made regarding the above subject matter.

Lou Anne Kling

LOU ANNE KLING
Assistant Administrator
Farmer Programs



Farmers Home Administration is an Equal Opportunity Lender.
Complaints of discrimination should be sent to:
Secretary of Agriculture, Washington, D.C. 20250

FH-
MAD

TYSON FOODS, INC.
HOLLY FARMS FRESH RETAIL DIVISION

1203 School Street, P.O. Box 88
 Wilkesboro, North Carolina 28697-0088 • Telephone: (919) 838-2171



June 24, 1994

Ambassador Mickey Kantor
 U. S. Trade Representative
 Office of U.S. Trade Representative
 600 17th Street, NW
 Washington, DC 20506

Dear Ambassador Kantor:

Tyson Foods believes continued growth in poultry export sales is vital to the economic well-being of the U. S. broiler industry and at the same time contributes positively to the general U.S. economy and balance of trade. Thus, when we see a potential problem that can seriously jeopardize an important export market for U.S. chicken it is of great concern. The current Canadian stance on U.S. poultry exports will have a significant and negative impact on our industry's exports.

More specifically in 1993 the United States exported to Canada over 56,000 metric tons of chicken and chicken products, making Canada one of our most important poultry export markets. When Canada filed with GATT its country schedule for the Uruguay Round, it stated a tariff-rate quota for chicken of 39,843.7 metric tons. This amount of 39,843.7 metric tons represents only about 70 percent of the 56,000 metric tons the United States exported to Canada last year. Further, the 39,843.7 tons when projected to 1995 would result in the United States having an estimated 6 percent of the Canada chicken market. According to the U.S./Canadian Free Trade Agreement, the United States is entitled to no less than 7.5 percent of the Canadian chicken market.

It was the U.S. poultry industry's understanding that the Uruguay Round negotiations were being conducted to increase international trade, not restrict it. Canada's unilateral action will result in a very unfortunate and unnecessary situation for the U.S. poultry industry.

U.S. poultry exporters are facing a sharply smaller export market to Canada with no prospect for a phase-out of Canadian trade restrictions. Further, if Canada retaliates as a result of U.S. action on Article XXVIII on Canadian exports to the United States, as Canadian government officials have indicated, the consequences for U.S. poultry exports could be even more severe than the cut-back to 6 percent already stated by Canada. Time is growing short for a satisfactory resolution of the U.S./Canadian poultry trade issue.

Feeding you like family.™

Ambassador Mickey Kantor

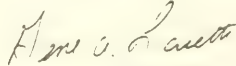
Page 2

June 24, 1994

I respectfully request that you and your office work toward a timely and appropriate resolution of this issue. Without prompt and effective action by our government, I believe the situation will not only remain unresolved, but severely worsen for U.S. poultry exporters.

Sincerely,

TYSON FOODS, INC.

A handwritten signature in dark ink, appearing to read "Gene A. Lovette".

Gene A. Lovette, Vice President
Fresh Retail Division

se

cc: Mike Espy, Secretary of Agriculture
National Broiler Council

FEB 20 1992

Mr. Truley Ponder
Tyson Foods, Inc.
P.O. Box 8
Shelbyville, Tennessee 37160

Official Files
Office of the Secretary
Field Office of the
National Poultry Improvement
Plan

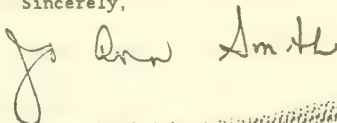
Dear Mr. Ponder:

Thank you for your letter of February 4, 1992, concerning several aspects of the National Poultry Improvement Plan (NPIP).

It is always a pleasure to hear from industry representatives, and I appreciate the opportunity to respond to your concerns. We recognize your interest in modifications to the provisions of the NPIP and wish to assure you that we have made this matter a top priority. Officials of our Animal and Plant Health Inspection Service (APHIS) will proceed expeditiously. We will take your suggestion regarding State authorization for the Biennial Plan Conference into consideration for future conferences. It is our belief that the Salmonella enteritidis prevention program can be administered like the NPIP with APHIS acting as coordinator for the States and industry, and we have taken note of your support.

We are pleased with the success of the NPIP throughout the country and the degree of cooperation enjoyed by the poultry industry and the Department. We are confident that the plan, along with APHIS' disease control activities, will continue to ensure the health of U.S. poultry.

Sincerely,



Jo Ann R. Smith
Assistant Secretary
Marketing and Inspection Services

cc:

Jo Ann Smith, MIS, Wash., DC
Executive Secretariat, Wash., DC
R. Melland, OA, Wash., DC
L. J. King, VS, Wash., DC w/cy of inc.
S. A. Liska, LPA, Hyatts., MD w/cy of inc.

Robert Melland
/s/ Robert Melland
Assistant Secretary

APHIS:LPA:SScheidhauer:ih:436-7776:2/14/92
SOURCE: ARhorer, VS

Clearances:

EC _____
LPA _____
VS _____
OA _____

Date Archived:

2/21/92

Original not mailed by
Office of the Executive
Secretary, USDA

35-C97331 FINAL CH192

SA
for Sally A. Liska
Compliance Control Officer
APHIS 2-17-92



CONTR 35

AGENCY

1992 FEB

SP-1015

Comments

Tyson Foods, Inc.

PO BOX 8 • SHELBYVILLE, TENNESSEE 37160 • TELEPHONE (615) 684-8180

February 4, 1992

The Honorable Edward Madigan
Secretary of Agriculture
United States Department of Agriculture
Agriculture Administration Building
Washington, D.C. 20250

The Honorable Edward Madigan:

I am writing this letter to enlist your help with the National Poultry Improvement Plan (NPIP). First, I would like to express my feelings as to the history and success of the NPIP. The plan is voluntary and accepted by the industry. It is almost self supporting, nice idea in the times we live. The plan is very successful in the State of Tennessee protecting both the commercial and novelty industry. The plan must be considered successful in the United States although there have been a few breaks. More audits by the senior coordinator would probably have prevented these breaks at very little added cost.

The items you can help the NPIP with are as follows. First, speed up the acceptance and printing of the approved changes voted on at the biannual Plan Conference. Second, allow the biannual Plan Conference to be held by its own authority as voted on by state programs and participants. Finally, the NPIP supports a SE prevention program that follows our current programs and not a federally administered program.

Sincerely,

Truley Ponder
Tyson Foods, Inc.

cc: Senator Jim Sasser
Senator Albert Gore
Congressman Jim Cooper



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

MAY 10 1953

John Tyson
P.O. Box 2020
Springdale, Arkansas 72765-2020

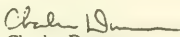
Dear Mr. John Tyson:

I have received your recent letter recommending Deborah Dawson for appointment as Deputy Assistant Secretary for Marketing and Inspection Service.

Please be assured that Ms. Dawson will be given careful consideration as the selection process continues.

Thank you for your personal interest in the Department.

Sincerely,


Charles Duncan
Executive Assistant
to the Secretary

THE WHITE HOUSE OFFICE
REFERRAL

APRIL 6, 1993

TO: DEPARTMENT OF AGRICULTURE

ACTION REQUESTED:
INFORMATION COPY - NO ACTION NECESSARY

DESCRIPTION OF INCOMING:

ID: 010018

MEDIA: LETTER, DATED MARCH 22, 1993

TO: PRESIDENT CLINTON

FROM: MR. JOHN TYSON
VICE CHAIRMAN FOR OPERATIONS
TYSON FOODS, INC.
POST OFFICE BOX 2020
SPRINGDALE AR 72765

SUBJECT: RECOMMENDS DEBORAH DAWSON FOR AN EXECUTIVE
POSITION AT THE U.S. DEPARTMENT OF
AGRICULTURE

PROMPT ACTION IS ESSENTIAL -- IF REQUIRED ACTION HAS NOT BEEN
TAKEN WITHIN 9 WORKING DAYS OF RECEIPT, PLEASE TELEPHONE THE
UNDERSIGNED AT 456-7486.

RETURN CORRESPONDENCE, WORKSHEET AND COPY OF RESPONSE
(OR DRAFT) TO:
AGENCY LIAISON, ROOM 91, THE WHITE HOUSE, 20500

JENNY MCCARTHY
DIRECTOR OF AGENCY LIAISON
PRESIDENTIAL CORRESPONDENCE

ID# 010018

THE WHITE HOUSE
CORRESPONDENCE TRACKING WORKSHEET

INCOMING

DATE RECEIVED: MARCH 30, 1993

NAME OF CORRESPONDENT: MR. JOHN TYSON

SUBJECT: RECOMMENDS DEBORAH DAWSON FOR AN EXECUTIVE
POSITION AT THE U.S. DEPARTMENT OF
AGRICULTURE

		ACTION		DISPOSITION	
ROUTE TO:	(STAFF NAME)	ACT CODE	DATE YY/MM/DD	TYPE RESP	C D COMPLETED YY/MM/DD
BRUCE LINDSEY		ORG	93/03/30	REL 1 A	93/03/31
<i>Agriculture</i>	REFERRAL NOTE: _____		93/03/31		24/1
	REFERRAL NOTE: _____				
	REFERRAL NOTE: _____				
	REFERRAL NOTE: _____				
	REFERRAL NOTE: _____				

COMMENTS: ENCLOSURE

ADDITIONAL CORRESPONDENTS: MEDIA: L INDIVIDUAL CODES: _____
 MI MAIL USER CODES: (A) _____ (B) _____ (C) _____

 *ACTION CODES: *DISPOSITION *OUTGOING *
 * * *CORRESPONDENCE: *
 *A-APPROPRIATE ACTION *A-ANSWERED *TYPE RESP=INITIALS *
 *C-COMMENT/RECOM *B-NON-SPEC-REFERRAL * OF SIGNER *
 *D-DRAFT RESPONSE *C-COMPLETED * CODE = A *
 *F-FURNISH FACT SHEET *S-SUSPENDED *COMPLETED = DATE OF *
 *I-INFO COPY/NO ACT NEC * * OUTGOING *
 *R-DIRECT REPLY W/COPY * * *
 *S-FOR-SIGNATURE * * *
 *X-INTERIM REPLY * * *

REFER QUESTIONS AND ROUTING UPDATES TO CENTRAL REFERENCE
 (ROOM 75, OEOB) EXT-2590
 KEEP THIS WORKSHEET ATTACHED TO THE ORIGINAL INCOMING
 LETTER AT ALL TIMES AND SEND COMPLETED RECORD TO RECORDS
 MANAGEMENT.

SCANNED

DEBORAH A. DAWSON

Resume

Page Three

EDUCATION:

The George Mason University School of Law, Fairfax, Virginia
Juris Doctorate, May 1988

The George Washington University, Washington, D.C.
Graduate Study: Business, Economics, January 1980 to May 1981

University of Colorado, Boulder, Colorado
Bachelor of Arts: Philosophy, Political Science, December 1974

L'Institut D'Etudes Europeennes, Paris, France
French Literature and Philosophy, 1973 to 1974

ADDITIONAL BACKGROUND AND EXPERIENCE:

- . Top Secret Security Clearance.
- . Library of Congress Legislative Institute Panelist and Speaker.
- . Free-lance editing and writing; published articles.
- . Campaign fundraising and ballot-entry petition organizer for state elections.
- . Democratic Congressional and Presidential campaign volunteer activities.
- . English and French language tutor; volunteer for community health service agencies.
- . Legal intern with the U.S. House of Representatives Committee on the Judiciary.

REFERENCES:

Upon request.

DEBORAH A. DAWSON
Resume
Page Two

Honorable Jerry M. Patterson, California
U.S. House of Representatives, Washington, D.C.
March 1981 to January 1985

Legislative Assistant. Researched issues and prepared legislation on a wide variety of issues, including: public works, transportation, immigration, education, health, and judicial matters. Drafted background briefs, committee and floor statements, press releases, and articles. Supervised legislative researchers, correspondents, and caseworkers. Organized all aspects of Washington and district field hearings hosted by Congressman. Liaison between local organizations and federal agencies on grant programs, local projects, and federal policies.

House Administration Committee
U.S. House of Representatives, Washington, D.C.
February 1977 to March 1981

Legislative Research Coordinator. Conducted research for Congress, Executive agencies, and private sector organizations on federal issues; prepared reports on legislative, parliamentary, and committee jurisdictional histories and procedures. Developed information system manuals, office procedures, and fiscal year appropriations justifications. Completed ad hoc short- and long-term projects for the Select Committee on Committees, the Select Committee on Narcotics, and other Standing Committees of the House using numerous information system databases. Supervised research staff of 16 employees working with technical and legislative offices of the House, Senate, and Library of Congress.

Payroll 1, Inc., Detroit, Michigan
February 1976 to January 1977

Client Consultant and Manager of accounting and tax records for the wide variety of businesses employing rapidly expanding computerized payroll and tax service. Supervised office operations; prepared client cost proposals; and managed business record conversions.

The Video Group, Inc., Detroit, Michigan
September 1975 to February 1976

Research and Executive Assistant. Prepared proposals for client programs broadcast on public and commercial television and radio. Drafted scripts; designed company brochures; implemented market surveys and advertising promotions; scheduled and delegated production crew assignments.

DEBORAH A. DAWSON
 2805 Arlington Boulevard
 Arlington, Virginia 22201
 (703) 243-6837
 (202) 226-3514

EMPLOYMENT EXPERIENCE:

House Committee on Merchant Marine and Fisheries
 U.S. House of Representatives, Washington, D.C.
 March 1991 to February 1993

Counsel/Subcommittee Director. Develop and negotiate authorization legislation under the jurisdiction of the Subcommittee on Oceanography, Great Lakes and the Outer Continental Shelf. Perform special projects for the Subcommittee on Fisheries Management. Schedule hearings, coordinate markups, supervise staff, and prepare Chairman and Subcommittee Members for floor debates. Draft speeches, articles, press releases, and reports. Legislative issues include: oceanographic research and coastal zone management; clean water; pollution damage; wetlands; marine and estuarine sanctuary programs; and oil and gas leasing.

Senate Committee on Appropriations
 U.S. Senate, Washington, D.C.
 February 1987 to March 1991

Professional Committee Staff Member. Prepared official documents for \$55 billion fiscal year and supplemental appropriations legislation. Briefed Senators and associate staff on Subcommittee and full Committee hearings and mark-up sessions. Drafted report language, speeches, and memoranda making policy recommendations for Senators during Committee, floor, and conference consideration of appropriations legislation. Served as one of two professional staff on the Subcommittee on Agriculture, Rural Development and Related Agencies. Primary reviewer and overseer of designated agency accounts of the U.S. Department of Agriculture, the Food and Drug Administration, and the Commodity Futures Trading Commission. Concentration on funding, regulatory, and legislative issues involving: agricultural trade and food assistance; research, marketing and inspection; food, drug, and medical device approval and safety programs.

House Committee on Agriculture
 U.S. House of Representatives, Washington, D.C.
 February 1985 to February 1987

Professional Committee Staff Member. Coordinated hearings and mark-up sessions for reauthorization and oversight of programs within the jurisdiction of the Subcommittee on Domestic Marketing, Consumer Relations, and Nutrition, and the Subcommittee on Department Operations and Foreign Agriculture. Drafted Committee reports and prepared Chairmen's statements for Committee and floor debates. Negotiated conference agreements and drafted final language for various titles of the five-year omnibus Food Security Act of 1985.



Tyson Foods, Inc. P.O. BOX 2020 • Springdale, AR 72765-2020 • Phone (501) 756-4000

March 22, 1993

The Honorable William J. Clinton
President of the United States
The White House
Washington, DC 20500

Action Office: ula
Referral Code: 6



* 3 0 2 0 4 7 5 *

Dear Mr. President: *Bill*

As you look for qualified staff to serve in your Administration, I would like to offer my support for the application of Deborah Dawson for an executive position at the U.S. Department of Agriculture. A copy of her resume is attached.

Deborah has served as a Democratic professional staff member on various committees of the Congress for more than a decade and a half. Deborah has worked effectively on agriculture trade and food safety policy and budget issues for over six years. During this time, she visited Arkansas several times to learn about various aspects of our State's agriculture production, processing and research.

I believe Deborah Dawson would be a superb choice for the position of Deputy Assistant Secretary for Marketing and Inspection at the U.S. Department Agriculture. I know she would bring good judgment, substantive experience, and enthusiasm to the job.

Please consider my strong recommendation of Deborah as you and Secretary Espy make the selection for this and other important policy positions at the Department of Agriculture.

Sincerely,

John Tyson
Vice Chairman for Operations

cc Honorable Mike Espy
Secretary of Agriculture

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OCT 06 1993

Mr. William B. Sturgis ✓
Cryovac Division W.R. Grace & Company
Duncan, South Carolina 29334

Dear Mr. Sturgis:

Secretary Espy has asked me to respond to your letter about the interim final rule published in the August 16, 1993, Federal Register to require safe handling instructions on the labels of raw or partially cooked meat and poultry products.

The public comment period on the rule ended September 15, 1993. We appreciate having your views and have included them in the record of public comments on the rule. After consideration of all comments received by the Department, we will publish a public notice of changes, if any, that are warranted by the comments received.

If you have questions, please let us know.

Sincerely,



H. Russell Cross
Administrator

cc: OES
FSIS Hearing Clerk
ECSAO

FSIS:ECSAO:DHenry:9/20/93:720-9520:tw:10/05/93:

✓ 03-3038637 03-3038753

File: Labeling: Handling
(OPI:S&T)

Identical letter sent to persons on attached list.

Mr. William B. Sturgis
Cryovac Divison W.R. Grace & Company
Duncan, South Carolina 29334

* Mr. Tom Harpenau
Vice President of Operations
Beef & Pork Division
Tyson Foods, Inc.
P.O. Box 2020
Springdale, Arizona 72765-2020

100-40
OFFICE OF THE EXECUTIVE
SECRETARIAT, USDA

1993 SEP 16 A 10 27

COPIES: _____



BEEF & PORK
DIVISION

Tyson Foods, Inc. 2210 Oakdawn Drive • P.O. Box 2020 • Springdale, AR 72765-2020 • 1-800-643-3410

September 8, 1993

The Honorable Mike Espy
Secretary
Department of Agriculture
Washington, DC 20250

Dear Mr. Secretary:

I am writing to you with regard to the interim final rule for Mandatory Safe Food Handling Statements on Labeling of Raw Meat and Poultry Products (Docket 93-0121), that was issued by the Department of Agriculture on August 16.

I support the inclusion of safe handling statements on all raw meat and poultry products, but oppose the unreasonable short time allowed to implement the rule and the fact that it was issued without providing for a prior public comment period that could substantially alter aspects of its implementation.

Specifically, I would like to request that the rule be modified in the following ways: 1) Focus the initial implementation schedule on ground products that do not currently have cooking and handling instructions, 2) Harmonize the effective date for mandatory safe handling statements and nutritional labeling of meat and poultry products effective July 6, 1994, 3) Use signs, placards and point-of-purchase materials to inform consumers during the implementation phase, 4) Develop a single safe handling statement for foodservice and retail establishments, and, 5) Use date of packaging to determine compliance.

Thank you for your consideration of my views on this matter.

Sincerely,

Tom Harpenau
V.P. of Operations
Beef & Pork Division

TH/raj

Action Office: fsis
Referral Code: 3



* 3 0 3 8 7 5 3 *

DOING OUR BEST...JUST FOR YOU.®



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

May 4, 1994

Mr. Bob Milton
Division Personnel Manager
Tyson Foods, Inc.
P.O. Box 2020
Springdale, Arkansas 72765-2020

Dear Mr. Milton:

Thank you for your letter concerning my plan to reorganize the Department of Agriculture (USDA). I appreciate your concerns with that part of the plan which would transfer the policy guidance for conservation programs to the new Natural Resources Conservation Service (NRCS), and I understand your belief that the Nation's farmers and ranchers should protect our natural resources. I hope this letter will respond to your concerns and explain why it is so important that we dramatically alter the way USDA does business.

USDA has become increasingly subject to intense criticism from Members of Congress, the media, the general public, and most importantly, from the very customers we are obligated to serve. We have been denounced as wasteful and extravagant, unresponsive to our increasingly diverse clientele, and organizationally and managerially incapable of meeting the challenges which face the food and agricultural sector, rural America, and our Nation's natural resource base.

As we embark upon the 21st century, we must acknowledge the validity contained in those criticisms and move toward constructive change. In this period of extraordinary transition, we are challenged to shrink Government while maintaining services. We must modify the way work gets done so that it accomplishes more and costs less. We have the opportunity to change, in a positive manner, the way USDA does business. A thoughtful reorganization of USDA into sharply focused, coordinated service agencies will prepare us for the next year, and the next century.

Under the proposed reorganization, USDA would be restructured along six mission lines to create a streamlined and revitalized Department. A new emphasis on conservation programs will be a part of the new USDA. A comprehensive program of conservation will be the primary responsibility of the new NRCS under the Assistant Secretary for Natural Resources and Environment. However, NRCS and a new single agency, the Farm Service Agency (FSA), will be under one roof working out of field service centers with continued involvement in the day-to-day administration of cost-share programs.

I am very committed to a close and cooperative relationship between NRCS and FSA at headquarters and, most importantly, in field offices to ensure that "one-stop shopping" becomes a reality. At the county level,

Mr. Bob Milton

2

NRCS and FSA will be collocated at field service centers, supported by the Info-Share Program, which will integrate common automated data bases, farm records systems, and agency accounting systems.

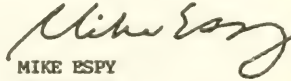
Farmers will work with FSA employees to sign up for USDA conservation cost-share programs. In addition, we are proposing to establish an agricultural conservation committee at each USDA field service center with equal representation from FSA county committees and soil and water conservation districts. These committees will have the authority to approve NRCS recommendations on individual cost-share applications. The current Agricultural Stabilization and Conservation Service (ASCS) system will be used to make cost-share payments to program participants.

I assure you that the system of local farmer-elected committees will be continued. In addition to the agricultural conservation committees that I have just described, new FSA county or area committees will be formed to replace the current ASCS and Farmers Home Administration committees and will assume their functions for the credit, price, and income support programs administered by FSA. They will also have many responsibilities in the operation of USDA conservation programs. One committee will be formed for each FSA field service center to represent and assume responsibilities for the area served by the FSA office. These committees will be comprised of five members, three elected by the farmers in the area and two appointed by the Secretary.

USDA is aware of the unique capabilities these committees have to reflect local needs and to exercise local responsibility. On the other hand, USDA is aware of the need to manage Federal conservation program budget resources with a national perspective to assure that the most critical needs are given priority. We will be working hard to find the appropriate balance between these concerns.

Thank you for sharing your concerns about my reorganization proposal. You can be sure that the concerns you express will receive every consideration as we develop procedures to realize an improved and more efficient USDA.

Sincerely,


MIKE ESPY
Secretary

Action Office: ascs
Referral Code: 2



Tyson Foods, Inc. P.O. Box 2020 • Springdale, AR 72765-2020 • Phone (501) 290-4000

November 5, 1993

Secretary Mike Espy
Department of Agriculture
14th & Independence, SW-Room 200A
Washington, D.C. 20250

Dear Secretary Espy:

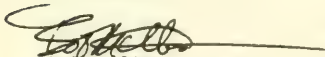
I ask that you vote against H.R. 3171. I believe ASCS should continue to administer the conservation program. ASCS has the expertise to administer the program, as they have demonstrated the past 50 years with minimal personnel cost while maintaining an excellent relationship with the nation's farmers.

It is not the role of SCS, the USDA, or a new government agency (ie. Office of Agricultural Environmental Quality) to protect our nation's natural resources. It is the role of the farmers and ranchers who have nourished this land and produced the food for this nation to continue to do what they do best; that is to continue looking after our natural resources.

As a nation we do not need another federal regulatory agency to watch over the farmer or anyone else as proposed by H.R. 3171. The SCS does not have the expertise to deal with the farmers as proposed by H.R. 3171.

I have been farming and ranching for 37 years in Kay County, Oklahoma, and Benton County, Arkansas. During this time I utilized the services of the ASCS extensively.

Sincerely,


Bob Milton
Division Personnel Manager

BM/dsr

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March 15, 1994

Mr. Leland Tollett
President and CEO
Tyson Foods, Inc.
P.O. Box 2020
Springdale, Arkansas 72765-2020

Dear Mr. Tollett:

Thank you for your letter to Secretary Espy expressing your concern over the status of our Agricultural Trade Offices (ATO) in Osaka and Tokyo, Japan. I regret the delay in responding.

We intent to continue to have ATOs in both these cities. I appreciate hearing about the benefits our ATOs have provided Tyson Foods in promoting U.S. agricultural products in Japan.

Sincerely,



Richard B. Schroeter
Acting Administrator

DRAFT:FAS:Robert Cummings:pr:3/8/94:401-7644:03-3048723
cc: OES, RCummings

1994 JAN 13 A 8:35

CO

Tyson**Tyson Foods, Inc.** P.O. Box 2020 • Springdale, AR 72765-2020 • Phone (501) 290-4000

January 5, 1994

The Honorable Mike Espy
 Secretary
 Department of Agriculture
 Administration Building
 14th Street & Independence Ave. SW
 Washington, DC 20250

Action Office: fas
 Referral Code: 3



• 3 0 4 8 7 2 3 •

Dear Secretary Espy:

Tyson Foods recently learned from our office in Japan and at an FAS co-operator meeting in Richmond that FAS may be planning to close one or both of its Agricultural Trade Offices in Japan as a cost saving measure. We would like to take this opportunity to reaffirm our support of the ATO offices in Japan and to iterate our belief that they are useful and effective in promoting U.S. agricultural products. Along with many other U.S. food processors, Tysons has made considerable use of the ATO facilities and services in Japan. In the last year alone, Tyson Foods used the Tokyo seminar and kitchen rooms to host two weeks of special sample shows with major Japanese customers such as 7-11 Japan, Wendy's Japan, KFC Japan, Daiei and Ito-Yokado. We also used it in April for our Chairman, Don Tyson, to conduct a press conference attended by over 50 journalists. Similar activities are planned in 1994.

In Osaka where the ATO opened one and a half years ago, we participated this past spring in a week long major American Food Show co-ordinated and hosted by the Osaka ATO. We have plans to conduct sample shows at the Osaka ATO facility in early 1994.

These and other programs have resulted in several millions of dollars worth of additional exports for Tyson Foods. We believe the services offered by the ATO in Japan will help us to continue to expand sales to Japan, which last year imported over \$100 million worth of poultry products and over \$25 billion worth of U.S. agricultural products in total.

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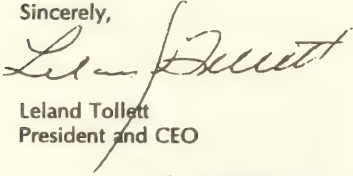
January 5, 1994

Mike Espy

Page 2

In summary, we believe strongly in the value of having Agricultural Trade Offices in Japan for the promotion of trade in U.S. agricultural products, and hope they will be continued in the future.

Sincerely,

A handwritten signature in dark ink, appearing to read "Leland Tollett", written in a cursive style.

Leland Tollett
President and CEO

cc John Vaillancourt, Tyson Sales Director for Japan
 Jeff McNeill, Tyson Japan
 Philip L. Mackie



APR 26 1993
P.O. Box 1446 □ 321 South Victory Street
Little Rock, Arkansas 72203-1446 □ (501) 375-8131 □ FAX 375-5519

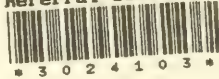
DAVID EVANS
President, Springdale

DON ALLEN
Executive Vice President

April 26, 1993

The Honorable Mike Espy
Secretary of Agriculture
Department of Agriculture
14th Street and Independence, S.W.
Washington, D.C. 20250

Action Office: osec
Referral Code: 6



Dear Secretary Espy:

The Arkansas Poultry Federation has scheduled a short meeting May 15 on the campus of Arkansas Tech University in Russellville, Arkansas, for the purpose of gaining insight into the Washington agricultural scene as it pertains to poultry production, processing, and inspection.

We invite you to participate with us in this endeavor. With the dramatic change in the executive branch of government, there is much for us to gain from such a meeting.

Representatives of the poultry producing companies in Arkansas are invited to attend as well as the Vice President - Agriculture, University of Arkansas, and the Director of Poultry Science Department, University of Arkansas. The official host of the event will be the Honorable L.L. Bryan, Speaker of the House of Representatives of Arkansas.

The meeting will begin at 9:00 a.m. in the private dining room of Chambers Cafeteria at Arkansas Tech.

We look forward to seeing you then.

Sincerely,

ARKANSAS POULTRY FEDERATION


Don Allen
Executive Vice President

DVA:rg

cc: David R. Evans

PAST PRESIDENT Lynch Butler Siloam Springs	SECRETARY David Purte Springdale	DIRECTORS Monty Henderson (1993) DeQueen Don Johnson (1993) Hot Springs Rex Thompson (1993) Fayetteville	Tom Vanenburg (1993) Batesville Leonard Kropp (1994) Hope Vic Evans (1996) Decatur	Joe Campbell (1995) Rogers Paul Lawrence (1995) Springdale Bob Pledger (1995) Denise	Paul Prudhomme (1995) Huntsville MEMBERS-AT-LARGE Ted Brewer (1994) Fayetteville Randall Goins (1994) Fort Smith
---	---	---	---	---	---



Tyson Foods, Inc. 2210 Oaklawn Drive • P.O. Box 2020 • Springdale, AR 72765-2020 • (501) 756-4000

January 4, 1993

Dr. H. Russell Cross
Administrator, FSIS
Room 331-E, Administrative Building
U.S. Department of Agriculture
Washington, DC 20250

Dear Russell,

Dr. James "Whit" Whitmore is retiring March 31, 1993 after more than thirty years in the poultry industry.

I'm sure that you have many fond and amusing stories of your association with Whit. Please take time to write him a letter recounting your favorite memories of how he touched your life.

Address your letter to Whit, but mail it to me at P.O. Box 2020, Springdale, AR, 72765 by February 15, 1993 so that we can have the letters bound into a book for him to read and re-read between golf games.

A letter with your normal letterhead and 1 1/2 inch margins on both the left and right side would be appreciated. Also, if you have other associates that have known Whit and would like to contribute, please pass this letter on to them.

Thanks for your help.

Ellis

Ellis W. Brunton, Ph.D.
Director, Technical Services
Tyson Foods, Inc.

EB/amh

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*Have letter prepared.
I have limited
experience with whit.
Contact others in agency
who have had more &
Quote them in letter.
JRC*

JAN 19 1993

Dr. James Whitmore
P.O. Box 2020
Springdale, Arkansas 72765

Dear Dr. Whitmore:

I am pleased to be among the many representatives from Government and industry to congratulate you on a long and successful career in the poultry industry. I wish you a healthy and productive retirement.

For many years, the Food Safety and Inspection Service (FSIS) has been aware of your commitment to the health of consumers through your leadership in the prevention of the contamination of food through pesticides, unapproved chemicals, and additives. Major among your contributions has been your support in promoting industry laboratory controls and your dedication to making a reality the new Tyson Foods laboratory for the testing of Tyson's products nationwide.

I was particularly pleased when you volunteered to participate in our Hazard Analysis and Critical Control Points (HACCP) Study of the Poultry Slaughter model. Your establishment was the only HACCP plant in the Southwestern Region. The success of this pilot program depends on cooperation with industry and officials such as you.

Dr. Joe Zurborg, Springdale Area Supervisor, has told me of your assistance in the FSIS total quality management meeting in Springdale last February. Your willingness to contribute when called on is greatly appreciated by FSIS officials who have worked with you over the years.

I want to extend my appreciation to you for all that you have accomplished on behalf of the poultry industry and to thank you for working cooperatively with FSIS. Please accept my best wishes to you and Mrs. Whitmore for continued success in the years ahead.

Sincerely,



H. Russell Cross
Administrator

Dr. James Whitmore

2

cc: ECSAO

FSIS:ECSAO:KatherineGibney/720-9520/1-14-93:jm:1/14/93:
0003-ADM-93

File: Miscellaneous
(OPI: ADM)

Information: JZurborg/IO/AO/(501) 751-8412;Previous Letter



Tyson Foods, Inc. P.O. Box 2020 • Springdale, AR 72765-2020 • Phone (501) 290-4000

TO: FSIS - Freedom of Information
 DATE: March 15, 1994
 SUBJ: FSIS DIRECTIVE 6550.1 12-09-93

94-268
 Rec'd
 3/23

ECS/10 received 3/23

The above directive has given Tyson Foods, Inc. reasons to believe the basis and/or objectives for its issuance are defective and invalid.

Please send: (1) The complete analytical basis for the pre-determined line speeds established on bird/carcass weight, (2) reason for Inspector's union - memorandum of understanding being attached and mailed to industry, (3) why presentation procedure now being used was not adjusted to reflect any valid objective needed to meet the Directive if any exist, (4) and finally the rationale for allowing FSIS Inspectors to use both hands to open a carcass for inspection and not mention any attention to the attached viscera. Apparently FSIS has not been enforcing the viscera presentation procedure. The place to determine presentation is at the post-mortem inspection station not the transfer belt.

Hopefully, the information requested can be provided as soon as possible.

Sincerely,

Dr. Eugene O'Neal Jr.
 Corporate Staff Veterinarian

cc: Dr. Craig Reed, Deputy Administrator
 Ms. Pat Stolf, Acting Deputy Administrator
 Dr. Larry Smith, S.W. Regional Deputy Director
 David Purtle
 Ellis Brunton
 Myer Westmoreland
 Aubrey Cusick

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APR 29 1994

Dr. Eugene O'Neal, Jr.
Tyson Foods, Inc.
P.O. Box 2020
Springdale, Arkansas 72765-2020

Dear Dr. O'Neal:

This is in response to your March 15, 1994, facsimile letter requesting the analytical basis for the predetermined line speeds established for heavy young chickens in Food Safety and Inspection Service Directive 6550.1.

As discussed in your conversation with Dr. Alice Thaler of our Slaughter Inspection Standards and Procedures Division, we are enclosing the information you requested. If you have any questions, you can call Dr. Thaler at Area Code (202) 720-3219.

Sincerely,

/S/ DOROTHY HENRY

Dorothy Henry, Director
Executive Correspondence
and Special Assignments Office
Information and Legislative Affairs

Enclosures

March 8, 1993 memo

Maximum Linespeed Computation - 1986 (9-1 configuration)

Roasters

Maximum Linespeed Computation - 1986 (27-1 configuration)

January 14, 1993 NAFV comments

cc: A. Thaler, SISP (w/copy of incoming)
ECSAO

FSIS:ECSAO:KRobbins:720-9520:4/29/94:jm:04/29/94:O'NealJr:
0150-OA-94

File: Inspection Procedures
(OPI: S&T/SISP)

Information: A. Thaler/SISPD/IO/720-3219

TO	HRC	DATE	11/11	TIME	AM
FROM	Jim Fisher	AREA CODE			PM
OF		NO.	1102 -		
		EXT.	2775		
MESSAGE					
Left message on					
Car's machine					
SIGNED <i>EJ</i>					
PHONED	<input checked="" type="checkbox"/>	CALL BACK	<input checked="" type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>
WANTS TO SEE YOU	<input type="checkbox"/>	WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>
URGENT	<input type="checkbox"/>				

TO	HRC	DATE	11/12	TIME	AM
FROM	Jack W. Fisher	AREA CODE			PM
OF		NO.			
		EXT.			
MESSAGE					
re: Typewriter plant -					
ref'd to Reed					
SIGNED <i>EJ</i>					
PHONED	<input type="checkbox"/>	CALL BACK	<input type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>
WANTS TO SEE YOU	<input type="checkbox"/>	WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>
URGENT	<input type="checkbox"/>				

TO	Bill	DATE	11/12	TIME	AM
FROM	Karen Fisher	AREA CODE			PM
OF		NO.	770 -		
		EXT.	377		
MESSAGE					
SIGNED <i>EJ</i>					
PHONED	<input type="checkbox"/>	CALL BACK	<input type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>
WANTS TO SEE YOU	<input type="checkbox"/>	WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>
URGENT	<input type="checkbox"/>				

TO	Bill	DATE	11/12	TIME	AM
FROM	Karen Fisher	AREA CODE			PM
OF		NO.	770 -		
		EXT.	3044		
MESSAGE					
SIGNED <i>EJ</i>					

An Anytime International Company

Aligner

REORDER NO 50-176

Aligner Professional Line

REORDER NO 50-176

ROG
ed in U.S.A. ©1986 Aligner

DATE TIME AM

TO	Mike	DATE	11/18	TIME	10:00	AM
FROM	Jack Wilkin	AREA CODE				
OF		NO.	544-6018			
EXT.						
MESSAGE						
has someone from						
Tiguanis for you to talk						
with -						
						SIGNED
						EF
PHONED	<input type="checkbox"/>	CALL BACK	<input checked="" type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>	WANTS TO SEE YOU
WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>	URGENT	<input type="checkbox"/>	

TO	Mike	DATE	11/18	TIME	11:00	AM
FROM	Pat Steefa	AREA CODE				
OF		NO.				
EXT.						
MESSAGE						
She says need to talk						
with you						
						SIGNED
						EF
PHONED	<input type="checkbox"/>	CALL BACK	<input checked="" type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>	WANTS TO SEE YOU
WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>	URGENT	<input type="checkbox"/>	

TO	David	DATE		TIME		AM
FROM	Scott Sapia	AREA CODE				
OF		NO.	1120			
EXT.	2003					
MESSAGE						
re Puerto Rico						
regulation						
						SIGNED
						EF
PHONED	<input type="checkbox"/>	CALL BACK	<input checked="" type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>	WANTS TO SEE YOU
WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>	URGENT	<input type="checkbox"/>	

TO	Mike	DATE	11/18	TIME	11:00	AM
FROM	Marion	AREA CODE				
OF		NO.				
EXT.						
MESSAGE						
Spec Asst to the						
President						
						SIGNED
						EF
PHONED	<input type="checkbox"/>	CALL BACK	<input checked="" type="checkbox"/>	RETURNED CALL	<input type="checkbox"/>	WANTS TO SEE YOU
WILL CALL AGAIN	<input type="checkbox"/>	WAS IN	<input type="checkbox"/>	URGENT	<input type="checkbox"/>	

Agner Professional Line

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REORDER NO. 50-176

ROC

Agner Professional Line

REORDER NO. 50-176

ROC

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THE SECRETARY OF AGRICULTURE
WASHINGTON, D. C.
20250-0100

AUG 5 1994

The Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources and Intergovernmental Relations
House Committee on Government Operations
Washington, DC 20515

Dear Chairman Towns:

I am providing the enclosed information in further response to your letter dated June 23, 1994. The request asks for "[c]opies of all written correspondence and a list of meetings, telephone calls and other communications between USDA administrators, including Mr. Richard Rominger, Deputy Secretary, and Tyson Foods, Inc., and the Arkansas Poultry Federation from January 20, 1992 through June 1, 1994, especially any communication between September 23, 1993 and April 1, 1994."

As you know, the Department made a response to your request on July 1, 1994 by providing copies of various documents. Subsequent discussions with your staff indicate that a broader request to include myself, the Under, and Assistant Secretaries was also intended.

Enclosure 1 includes a list from my schedule which is responsive to your request. Several meetings are identified with Mr. Jack Williams, a consultant who represents a number of clients, including Tyson Foods, Inc. Because Mr. Williams represents clients other than Tyson Foods, all meetings listed did not include a discussion of issues or concerns related to that organization. I would also point out that my schedule, when viewed in its entirety, reflects the open door policy that I have maintained since becoming Secretary. I have had numerous meetings with both USDA employees and all others interested in issues before the Department.

Enclosure 2 includes information concerning contacts with Gene Branstool, former Assistant Secretary for Marketing and Inspection Services, which are responsive to your request.

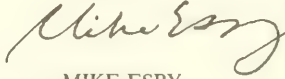
The Honorable Edolphus Towns

2

Enclosure 3 includes a response to your request as provided by Deputy Assistant Secretary for Marketing and Inspection Services, Ms. Patricia Jensen.

No other records of contacts have been identified which are responsive to your request.

Sincerely,

A handwritten signature in cursive script that reads "Mike Espy". The signature is written in dark ink and is positioned above the printed name.

MIKE ESPY

Enclosures

Enclosure 1
Response for Chairman Edolphus Towns
Subcommittee on Human Resources and Intergovernmental Relations
House Committee on Government Operations
August 5, 1994

Secretary of Agriculture
Mike Espy

Wednesday, February 3, 1993, Meeting with Mr. Jack Williams, 1:00 p.m.

Thursday, March 11, 1993, Meeting with Mr. Jack Williams, 4:30 p.m.

Tuesday, April 27, 1993, Meeting with Mr. Jack Williams, 11:45 a.m.

Saturday, May 15, 1993, Meeting with Arkansas Poultry Federation, including representatives of Tyson Foods, Inc.

Tuesday, November 16, 1993, Meeting with Mr. Jack Williams, 3:00 p.m.

Sunday, January 16, 1994, Attended sports event. Mr. Don Tyson and Mr. John Tyson were present.

Tuesday, January 25, 1994, Meeting with Mr. Jack Williams, 3:30 p.m.

Wednesday, February 16, 1994, Meeting with Mr. Jack Williams, 4:00 p.m.

Enclosure 2
Response to Chairman Edolphus Towns
Subcommittee on Human Resources and Intergovernmental Relations
House Committee on Government Operations
August 5, 1994

Assistant Secretary for Marketing and Inspection Services
Gene Branstool

May 5, 1993, Meeting with Mr. John Tyson and Miles Goggins, 4:00 p.m.

June 8, 1993, Telephone call from Mr. John Tyson.

June 9, 1993, Telephone call from Mr. John Tyson.

Enclosure 3
Response to Chairman Edolphus Towns
Subcommittee on Human Resources and Intergovernmental Relations
House Committee on Government Operations
August 5, 1994

Deputy Assistant Secretary for Marketing and Inspection Services
Patricia Jensen

Wednesday, January 5, 1994, Telephone call from Jack Williams.

Wednesday, January 12, 1994, Meeting with Archie Schaeffer and Jack Williams,
11:45 a.m.

Friday, January 21, 1994, Telephone call from Jack Williams.

Tuesday, January 25, 1994, Telephone call from Jack Williams.

Tuesday, February 1, 1994, Met John Tyson, Don Tyson and other Tyson
representatives.

Wednesday, February 2, 1994, a.m. Addressed Arkansas Poultry Federation, including
representatives of Tyson Foods, Inc.; Toured Tyson poultry plant and research facility with
Archie Schaeffer and other Tyson officials.

Thursday, March 3, 1994, Telephone call from Jack Williams.

Friday, March 11, 1994, Telephone Call from Jack Williams.

NOTE: Telephone calls were often relative to Williams' client Mid America Dairy
Cooperative. There were some additional incoming phone calls which were
not recorded due to the fact that Ms. Jensen received the call as it was
placed.

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio

Bernard Sanders, Vermont
Independent

Majority (202) 225-2548

FAX (202) 225-2382

Minority (202) 225-2738

June 27, 1994

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

Dear Mr. Secretary:

As you are aware, in the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations jointly conducted a hearing on June 16, 1994, on the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. At the hearing, Mr. Richard Rominger, Deputy Secretary, testified that a Food Safety Inspection Service (FSIS) staff review and evaluation of scientific literature concerning temperature effects on poultry would be completed this month and presented to the National Advisory Committee on Microbiological Criteria for Foods (Micro Committee) for consideration at its meeting in July. Mr. Rominger testified that the Micro Committee's review, as well as other USDA efforts to determine consumer concerns and perceptions, would form the basis of any policy revision regarding labeling of "fresh" poultry.

Because the issue of "fresh" poultry has been the subject of intense consumer and industry interest, it is important that the Micro Committee be able to provide the level of impartial scientific advice that USDA is seeking. Therefore, we would appreciate your responses to the following questions by Friday, July 15, 1994:


- (1) What is the purpose, mission and authorization of the Micro Committee? What requirements and procedures apply to membership on the Committee?
- (2) What standards and tests of conflict of interest or appearance of conflict of interest apply to officers and members of the Micro Committee?
- (3) Are officers and members of the Micro Committee required to report financial disclosure information to USDA or any other sponsoring institution? If yes, what are the reporting requirements? Specifically, how is the information evaluated and by whom? If financial disclosure is not required, why not?

Secretary Espy
June 27, 1994
Page Two

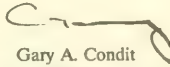
- (4) What requirements and procedures exist for members recusing themselves from matters in which they have a direct financial or other vested interest pending before the Micro Committee?
- (5) Who are the current members of the Micro Committee and what are their affiliations? Have any current members of the Micro Committee been involved in the "fresh" poultry controversy, and, if yes, who? Have these individuals recused themselves from participating in the upcoming Micro Committee deliberations on "fresh" poultry? If yes, who?
- (6) How will USDA ensure that the Micro Committee will be able to provide impartial scientific advice to USDA on the contentious "fresh" poultry issue?

We greatly appreciate your cooperation in this matter. If you have questions, please contact Bill Layden at 202/225-2548 or Ed Armstrong at 202/225-3741.

Sincerely,



Edolphus Towns
Chairman
Human Resources and
Intergovernmental Relations
Subcommittee



Gary A. Condit
Chairman
Information, Justice,
Transportation, and
Agriculture Subcommittee

cc: The Honorable Steven Schiff
The Honorable Craig Thomas
(Ranking Minority Members)



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your letter of June 27, 1994, co-signed by Congressman Gary A. Condit, the Department of Agriculture (USDA) provided certain information answering your questions on USDA's National Advisory Committee on Microbiological Criteria for Foods (Micro Committee). I regret that a letter of transmittal was not included with the package. The information previously provided was obtained from the Food Safety and Inspection Service Micro Committee staff office.

Included in the information was the Micro Committee charter as established by the Federal Advisory Committee Act (FACA); Departmental Regulation DR 1041-1, which establishes administrative procedures for the Micro Committee; and the Committee's list of members.

If you have any questions, please contact Ms. Patricia Jensen, Acting Assistant Secretary for Marketing and Inspection Services, who serves as the Micro Committee's chairperson. Her telephone number is (202) 720-4256.

Sincerely,

A handwritten signature in dark ink, appearing to read "Richard Rominger", is written over the typed name.

RICHARD ROMINGER
Deputy Secretary

U.S. DEPARTMENT OF AGRICULTURE
Food Safety and Inspection Service

Responses to Chairman Towns' and Chairman Condit's June 27, 1994
Questions on the National Advisory Committee on Microbiological
Criteria for Foods (Micro Committee)

July 20, 1994

1. What is the purpose, mission and authorization of the Micro Committee? What requirements and procedures apply to membership on the Committee?

The National Advisory Committee on Microbiological Criteria for Foods (the "Committee") is administered by the Food Safety and Inspection Service. The Committee was formed in 1987 in response to the recommendation of the National Academy of Sciences (NAS) that there should be established "an ad hoc Commission on Microbiological Criteria for Foods,"¹ and an expectation of the U.S. House of Representatives Committee on Appropriations that "the Food Safety and Inspection Service, in coordination with the Food and Drug Administration, move as quickly as possible in establishing a National Advisory Committee on Microbiological Quality Standards."² According to its charter, the Committee's purpose is to provide advice and recommendations on the development of microbiological criteria for foods.

This Advisory Committee is made up of scientists in food safety and human health disciplines from industry, public interest groups, academia and government. They are appointed by the Secretary of Agriculture after consultation with the Secretary of Health and Human Services. The criteria used to select new nominees and to retain current members of the Committee, based upon Departmental Regulation DR1041-1, are "that the membership of a Committee shall be fairly balanced in terms of the points of view represented and the functions to be performed. For purposes of obtaining balance, agencies shall consider for membership a cross-section of interested persons and groups with demonstrated professional or personal qualifications or experience to contribute to the functions and tasks to be performed." In its most recent composition, the Committee consisted of 8 members who were representatives of state governments, 9 members representative of academia, and 9 members representative of industry or non-governmental organizations. All of the members except two are either Ph.D.'s, M.D.'s or DVM's.

2. What standards and tests of conflict of interest or appearance of conflict of interest apply to officers and members of the Micro Committee? The members of the committee serve as representatives of academia, private industry and other non-governmental organizations as well as State and Federal government. They receive no compensation for their work on the committee, become committee members through a process of recommendations by outside organizations, and do not function as spokespersons for the Food Safety and Inspection Service. In this representative capacity, the conflict of interest statutes that, by their terms, apply to government employees and special government employees, do not apply to the Committee members.

The Committee's function as a scientific advisory body ensures that conflicts of interest will not arise in Committee deliberations. The advice provided is not policy advice, but rather is advice on the scientific merits of issues presented by the Department for the Committee's consideration. In addition, not more than one officer or employee of any corporation or other non-Federal entity at any one time without prior approval of the Committee Management Officer. As recommendations are developed and presented to the Department via consensus of several members of differing backgrounds, it would be difficult to have one or two individuals impose a specific position or agenda on the Committee.

3. Are officers and members of the Micro Committee required to report financial disclosure information to USDA or any other sponsoring institution? If yes, what are the reporting requirements? Specifically, how is the information evaluated and by whom? If financial disclosure is not required, why not?

Departmental Regulations require that a background clearance be conducted for all proposed Committee members to be appointed by the Secretary, except for those who are Federal employees. This investigation, which should consist of a name check and review of Department indices or files, is conducted by the Office of the Inspector General based upon information provided by Committee appointees on Form AD-755 (see attached). Form AD-755 includes a request to disclose any source of income in excess of \$10,000 during the preceding year (other than from the individual's primary employer, which is listed on the front of the form). The background investigation form is submitted to the Office of the Secretary for each proposed Committee member.

4. What requirements and procedures exist for members recusing themselves from matters in which they have a direct financial or other vested interest pending before the Micro Committee?

Since conflict of interest statutes do not apply to members, particular requirements and procedures for recusal have not been established. However, there is history of recusal within the Committee. In 1994, Dr. John Kvenberg of the Food and Drug Administration (FDA) recused himself when the Committee reviewed and provided comments on FDA's Proposed Rule to Establish Procedures for the Safe Processing and Importing of Fish and Fishery Products.

5. Who are the members of the Micro Committee and what are their affiliations? Have any current members of the Micro Committee been involved in the "fresh" poultry controversy, and if yes, who? Have these individuals recused themselves from participating in the upcoming Micro Committee deliberations on "fresh" poultry? If yes, who?

A list of members of the National Advisory Committee on Microbiological Criteria for Foods is attached. It should be noted that the Committee was rechartered on May 24, 1994) and, consequently, six of the Committee members (noted with an asterisk) are no longer active as they have reached the end of the six year tenure established in Departmental Regulation 1041-1. A new list of members is anticipated shortly. While there are members of the Committee whose affiliations would indicate that they have an interest in the "fresh" poultry issue, because the issue has not been formally placed before the Committee, no members of the Committee have as yet recused or been directed to recuse themselves.

6. How will USDA ensure that the Micro Committee will be able to provide impartial scientific advice to USDA on the contentious "fresh" poultry issue?

On May 24, 1994, the Secretary renewed the charter of the Micro Committee (see attached charter). The Department is in the process of appointing new members to serve on the Committee and reappointing certain members who are currently serving. Prior to the Committee's consideration of the "fresh" issue, the chairperson of the Committee, the Acting Assistant Secretary for Marketing and Inspection Services, will require members to disclose any interests and affiliations that are related or appear to be related to issues that may be before the Committee. Additionally, Committee members will be required, as a condition of appointment, to recuse themselves, either voluntarily or at the direction of the chairperson, from participation in matters in which they have actively been involved in their professional capacity. However, as noted above, it must be recognized that the Committee is purposefully composed of representatives of academia, public interest groups, government, and industry. In fact, the advice provided by this Committee is valuable precisely because such advice is the consensus reached by these diverse and informed groups. Therefore, the mere fact that a Committee member is employed by or affiliated with a regulated industry group is not a disqualifying factor per se.

The Committee's recommendations to the Secretary will represent a consensus opinion of scientists representing an entire spectrum of thought on issues of food biology. Additionally, the report of the Committee on the "fresh" issue will made available to the public.

The FSIS scientific literature review and analysis of the physiological and microbial effects on poultry of temperatures in the range of 40 degrees to 0 degrees fahrenheit will be referred to the Micro Committee for scientific peer review and comment. The Committee is being asked by USDA to review and comment on the comprehensiveness of the scientific literature review and analysis conducted by the FSIS, and the scientific validity of the facts presented in this review. The Department will not ask the Committee to make any recommendations on what the "fresh" policy should be.

As Chairperson of the Committee, the Assistant Secretary for Marketing and Inspection Services will personally meet with the Committee to receive its report on the "fresh" issue as soon as it is complete.

-
- 1 An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients (Washington, D.C.: National Academy of Sciences, National Academy Press, 1985), pp. 333-335.
 - 2 Appropriations Subcommittee on Rural Development, Agriculture and Related Agencies, Report 100-386, U.S. House of Representatives, October 20, 1987, p. 58.



United States
Department of
Agriculture

Office of
Personnel

DR 1041-1

Advisory Committee Management

February 8, 1993

DR 1041-1

TABLE OF CONTENTS

Section	Title	Page
1	Purpose	1
2	Cancellation	1
3	Policy	1
4	Definitions	1
5	Responsibilities	3
6	Exclusions From Provisions of the Act	5
7	Establishment or Reestablishment of a Nonstatutory Advisory Committee	6
8	Renewal of a Nonstatutory Committee	10
9	Termination of a Nonstatutory Advisory Committee	10
10	Establishment, Reestablishment and Renewal of a Statutory Committee	10
11	Membership	11
12	Clearance of Committee Members	14
13	Appointment of Members	15
14	Meetings	16
15	Disclosure of Official Information to Public Members	20
16	Reporting and Records	21
APPENDIX A	Form AD-241, Committee Control Record	A-1
APPENDIX B	Form AD-742, Transfer and Adjustment Voucher	B-1
APPENDIX C	Example of Advisory Committee Charter	C-1
APPENDIX D	Example of Federal Register Notice	D-1
APPENDIX E	Form AD-114, Secretary's Correspondence Jacket (Pink Jacket),	E-1
APPENDIX F	Form AD-116, Clearance and Approval for Departmental Directives (Blue Jacket)	F-1
APPENDIX G	Form AD-755, Advisory Committee Membership Background Information	G-1
APPENDIX H	Form AD-580, Certificate of Appointment	H-1

U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

DEPARTMENTAL REGULATION		NUMBER: 1041-1
SUBJECT: Advisory Committee Management	DATE: February 8, 1993	
	OPI: Executive Resources and Services Division	

1 **PURPOSE**

This regulation provides procedures for the establishment, operation, duration, and accessibility to the public of advisory committees under the jurisdiction of the Department.

2 **CANCELLATION**

This regulation supersedes DR 1041-1 dated November 13, 1989.

3 **POLICY**

- a All provisions of the Federal Advisory Committee Act (5 U.S.C. App.), Title XVIII of the Food and Agriculture Act of 1977, as amended (7 U.S.C. 2281 et. seq.), regulations issued by the Committee Management Secretariat of the General Services Administration (41 CFR Part 101-6) and these regulations will apply to all advisory committees, as that term is defined in these regulations, unless otherwise provided by law. The Department will maintain control over the establishment and use of advisory committees.
- b Unless otherwise provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Decisions regarding actions or policies relating to matters dealt with by an advisory committee shall be made solely by an official of the Department.

4 **DEFINITIONS**

- a Act. The Federal Advisory Committee Act, as amended.

DISTRIBUTION 10

- b Advisory committee. A committee, subcommittee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or subgroup thereof, established by statute, or established or utilized by the President or any Departmental official for the purpose of obtaining advice or recommendations on issues or policies within the scope of his/her responsibilities, which are not exempt from the Federal Advisory Committee Act. Refer to Section 6 for exclusions from the Act.
- c Committee Management Officer (CMO). The Assistant Secretary for Administration.
- d Nonstatutory advisory committee. An advisory committee established by Departmental authority, including those authorized by an Act of Congress.
- e Reestablishment of an advisory committee. The rechartering of a previously established committee after its charter has expired.
- f Renewal of an advisory committee. The rechartering of a previously established committee prior to the expiration of its current charter.
- g Secretariat. The Committee Management Secretariat of the General Services Administration (GSA).
- h Staff member. An individual who serves in a support capacity to an advisory committee.
- i Statutory advisory committee. An advisory committee established by an Act of Congress. It includes an advisory committee established by the Secretary where a statute allows no discretion as to whether the committee should be established.
- j Utilized. A committee or other group, composed in whole or in part of other than full-time Government officers or employees, which has an established existence outside the Federal Government and is used as a preferred source to obtain advice or recommendations in the same manner as from an established advisory committee.

February 9, 1993

DR 1041-1

5 RESPONSIBILITIES

a The CMO will be responsible for:

- (1) Exercising control and supervision over the establishment, procedures, and accomplishments of advisory committees;
- (2) Assigning responsibility for the assembly and maintenance of the reports, records, and other papers of advisory committees; and
- (3) Carrying out, on behalf of the Department, the provisions of Section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

b The Office of Personnel (OP) provides staff support for the CMO by:

- (1) Maintaining systematic information on the nature, functions, and operations of each advisory committee, including a complete set of charters and annual reports for advisory committees;
- (2) Filing advisory committee charters with the appropriate Congressional committees, the Library of Congress, and the Committee Management Secretariat;
- (3) Maintaining membership lists for all advisory committees;
- (4) Complying with advisory committee management reporting requirements; and
- (5) Providing advice and guidance on the establishment, renewal, utilization, management, and reporting of all advisory committees.

c The Office of Finance and Management (OFM) provides staff assistance in the preparation, implementation, and monitoring of all non-Forest Service advisory committee budgets by:

- (1) Consulting with agencies regarding the presentation of proposed committee budgets. A consolidated budget will be compiled for all non-Forest Service agencies and presented to the CMO, the Office of Management and Budget, and Congress;
 - (2) Consulting with the CMO, once the appropriation for advisory committees has been received, and then allocating funds to the appropriate Under Secretary or Assistant Secretary for the operation of committees within respective functional areas; and
 - (3) Issuing instructions to agencies for the preparation of quarterly reports indicating current rates of expenditure and forecasted fund requirement projections. These reports will be consolidated, and recommendations regarding reallocation of funds will be made to the CMO.
- d Agency heads are responsible for providing an orderly procedure for:
- (1) Establishing or terminating advisory committees and providing guidance for the selection of members;
 - (2) Adhering to the law and regulations governing the use of advisory committees;
 - (3) Designating for any advisory committee a central location for the assembling and maintenance of the reports, records, and other papers of the advisory committee for public inspection and copying;
 - (4) Conducting periodic reviews of advisory committee activities;
 - (5) Maintaining an adequate advisory committee control system, including maintaining records of all advisory committees sponsored by the agency;
 - (6) Submitting Form AD-241, Committee Control Record (Appendix A), and Form AD-742, Transfer and Adjustment Voucher (Appendix B), for all advisory committees; and

February 8, 1993

DR 1041-1

- (7) Appointing a designated agency official for each advisory committee.

6 EXCLUSIONS FROM PROVISIONS OF THE ACT

a Excluded from coverage under these regulations are:

- (1) A committee composed wholly of full-time officers or employees of the Federal Government;
- (2) Any advisory committee specifically exempted by an Act of Congress;
- (3) Any local civic group whose primary function is to render a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies;
- (4) Any meeting initiated by the President or one or more Federal officials for the purpose of obtaining advice or recommendations from one individual;
- (5) Any meeting initiated by a Federal official with more than one individual for the purpose of obtaining the advice of individual attendees and not for the purpose of using the group to obtain consensus advice or recommendations. Such a group would, however, be covered by these regulations if the deliberations of the group are accepted as a source of consensus advice or recommendations;
- (6) Any meeting initiated by a group with the President or one or more Federal officials for the purpose of expressing the group's view, provided the group is not used recurrently as a preferred source of advice or recommendations;
- (7) Meetings of two or more advisory committee or subcommittee members convened solely to gather information or conduct research for a chartered advisory committee, to analyze relevant issues and facts, or to draft proposed position papers for deliberation by the committee or subcommittee; and

- (8) Any meeting with a group initiated by the President or one or more Federal officials for the purpose of exchanging facts or information.

7 **ESTABLISHMENT OR REESTABLISHMENT OF A NONSTATUTORY ADVISORY COMMITTEE**

- a Policy on establishment or reestablishment. The following policy shall govern the establishment or reestablishment of nonstatutory advisory committees. No such committee shall be established or reestablished unless:
- (1) It has been determined as a matter of formal record, by the Secretary or appropriate Under or Assistant Secretary, to be in the public interest;
 - (2) It has been established or reestablished in accord with these regulations;
 - (3) Prior consultation with the Secretariat has been accomplished;
 - (4) Notice of the intent to establish or reestablish the committee has been published in the Federal Register at least 15 days before the committee's charter is filed, unless the Secretariat authorizes a shorter period between publication and charter filing;
 - (5) The purpose of the committee has been clearly defined;
 - (6) The proposed membership of the committee represents a balance in terms of the points of view represented and the functions to be performed; and
 - (7) The proposed budget of the committee reflects the reasonably anticipated costs of performing the functions of the committee, and the funds to support the committee's proposed activities are available within the Congressional limitation, as indicated by OFM appropriations.

February 8, 1993

DR 1041-1

b Procedure for establishment or reestablishment.

- (1) An agency desiring to establish or reestablish a committee or utilize an outside committee shall first consult with and obtain the approval of the appropriate Under or Assistant Secretary. If that official approves, the agency shall prepare the following documents:
 - (a) A letter for the signature of the CMO to the Director of the Secretariat containing the following information:
 - (i) An explanation of why the committee is essential to the conduct of agency business and in the public interest;
 - (ii) An explanation of why the committee's functions cannot be performed by the agency, another existing advisory committee, or other means such as a public hearing;
 - (iii) A description of the agency's plan to attain balanced membership;
 - (iv) A request for concurrence of the Secretariat in the Department's decision; and
 - (v) Two copies of the draft charter must be forwarded with the letter.
 - (b) A Departmental Regulation containing the following information which will serve as the charter for the committee (see Appendix C for an example):
 - (i) Committee name;
 - (ii) Committee's objectives and the scope of its activity;
 - (iii) Period of time necessary for the committee to carry out its purposes;
 - (iv) Official of the Department to whom the committee reports;

- (v) Agency responsible for providing necessary support for the committee;
 - (vi) Description of the duties for which the committee is responsible and, if such duties are not solely advisory, the authority for such functions;
 - (vii) Estimated annual operating costs in dollars and staff years;
 - (viii) Estimated frequency of committee meetings;
 - (ix) Termination date of the committee; and
 - (x) The following statement: "Equal opportunity practices, in line with USDA policies, will be followed in all membership appointments to the committee. To ensure that the recommendations of the committee have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities."
- (c) A notice for publication in the Federal Register of the Department's intent concerning the committee (see Appendix D for an example). The notice shall contain the name and purpose of the committee, and a statement that the committee is necessary and in the public interest. If desired, an agency may solicit comments in the notice by including the name and address of any agency official to whom the public may submit comments. Notices for national committees shall be for the signature of the CMO. Notices for regional, State, and local committees may be signed by an agency official.

February 8, 1993

DR 1041-1

- (2) Using the appropriate clearance forms, the letter to GSA, charter, and Federal Register notice shall be cleared within the agency and then forwarded, as a package, through the Office of the General Counsel (OGC) to OP. OP is responsible for obtaining all other Departmental clearances. AD-114 (pink jacket) shall be used for the letter (Appendix E); AD-116 (blue jacket) shall be used for both the Departmental Regulation and the Federal Register notice (Appendix F).
- (3) OP will notify the agency of the action taken by the Secretariat and will forward the Federal Register notice to the CMO for signature. The committee's charter will be forwarded for signature at the end of the 15-day notice period.
- (4) If an agency has not established or reestablished a committee within a year of the concurrence of the Secretariat, the concurrence shall be terminated unless the CMO grants an extension. In no case shall the approval extend beyond two years from the date of the concurrence

c Procedures for amending a committee charter.

- (1) When minor amendments to the charter are needed, the agency providing support to the committee will prepare a revised charter and forward it, through OGC, to OP. OP is responsible for obtaining clearances and filing the revised charter.
- (2) When major amendments are necessary, the agency will, in addition to the revised charter, prepare a letter to the Committee Management Secretariat explaining the purpose of the changes and why they are necessary. This letter will be prepared for the signature of the CMO. The Secretariat will have 15 days to review the amendment, after which the revised charter will be forwarded for signature and filed with the appropriate committees of Congress.

8 RENEWAL OF A NONSTATUTORY COMMITTEE

Procedure for renewal. Procedures in Sections 7a and 7b apply to the renewal of nonstatutory committees. The Federal Register notice will not be filed until after the charter has been filed, and will note that the committee has been renewed. The renewal process begins no more than 90 and no less than 40 days before a committee's scheduled termination date.

9 TERMINATION OF A NONSTATUTORY ADVISORY COMMITTEE

a A committee shall be terminated for the following reasons:

- (1) The charter has expired and the committee has not been renewed or reestablished as provided in these regulations;
- (2) The committee has expended funds in excess of its estimated annual operating costs by more than 10 percent or \$500, whichever is greater, without prior approval of the CMO;
- (3) The committee has not filed all reports required under provisions of the Act or the Food and Agriculture Act of 1977, as amended;
- (4) The committee has not met for two consecutive years;
- (5) The functions of the committee could or should be performed by Federal employees; and
- (6) The committee does not serve or has ceased to serve an essential function.

10 ESTABLISHMENT, REESTABLISHMENT, AND RENEWAL OF A STATUTORY ADVISORY COMMITTEE

- a The filing of a charter is the only action required to establish, reestablish, or renew a statutory advisory committee. The charter shall contain the same information as required for a nonstatutory committee in Section 7b(1)(b), and shall be forwarded to OP, through OGC. OP is responsible for obtaining Departmental clearances, signature, and filing.

February 8, 1993

DR 1041-1

- b For a statutory advisory committee whose duration is set by law for more than two years, a new charter must be filed every two years after the date of enactment of the law establishing the committee.
- c A statutory advisory committee whose duration is not otherwise provided for by law shall terminate two years after the date of enactment of the law establishing the committee. To reestablish such a committee, use the procedures for nonstatutory committees listed in Section 7.

11 MEMBERSHIP

- a General procedures. The following procedures apply to all advisory committees:
 - (1) The membership of a committee shall be fairly balanced in terms of the points of view represented and the functions to be performed. For purposes of obtaining balance, agencies shall consider for membership a cross-section of interested persons and groups with demonstrated professional or personal qualifications or experience to contribute to the functions and tasks to be performed.
 - (2) No member, other than an officer or employee of the Department, shall serve on more than one committee at any one time without the prior approval of the CMO. The Office of the Secretary will notify the agency when a nominee is already serving on another advisory committee. Requests for multiple memberships shall be submitted through OP.
 - (3) Not more than one officer or employee of any corporation or other non-Federal entity, including its subsidiaries and affiliates, shall serve on the same advisory committee at any one time without the prior approval of the CMO. Requests shall be submitted through OP.
 - (4) No member, other than an officer or employee of the Department, may serve on an advisory committee for more than six consecutive years without the prior approval of the CMO. Requests shall be submitted through OP.

- (5) Appointments of members shall be for no longer than two years or for the unexpired term of the member being replaced, as appropriate.
- (6) Committee appointments expire when the committee charter expires except in those instances where length of membership term is directed by law. The appointing authority, however, may terminate an appointment at an earlier time. In this connection, agencies should monitor the attendance and participation of committee members and consider replacing any member who has missed a substantial number of scheduled committee meetings.
- (7) There shall be no discrimination on the basis of race, color, national origin, religion, disability, age, or sex in the selection of members. If the agency publishes a notice in the Federal Register soliciting nominees for committee membership, the notice shall include the following statement: "To ensure that recommendations of the (committee/council/board) take into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities."
- (8) In the event a committee is renewed or reestablished, new appointments to the committee shall be necessary. New appointments shall provide for rotation to the extent feasible and practicable. Reappointments may be made to assure effectiveness and continuity of operations consistent with the above restraints.
- (9) It shall be the responsibility of the agency to insure that no person selected as a member of a committee is engaged in employment or has a financial interest which is deemed likely to affect the integrity of his/her service on the committee.

February 8, 1993

DR 1041-1

b Compensation and expense reimbursement.

- (1) Unless specifically required by law or approved by the CMO, agencies shall not compensate committee members for their service on a committee.
 - (a) If compensation is mandated by statute, but the statute does not specify a rate of compensation, the agency shall recommend to the CMO the rate of pay for members. The recommendation shall be forwarded through OP. If approved, OP will notify the agency.
 - (b) If compensation is not mandated by statute and the agency desires to pay members, the request shall be forwarded to the CMO through OP. The request shall include justification for such payment and the proposed rate of pay. If approved, OP will notify the agency.
 - (c) The rate of pay in either (a) or (b) above shall not exceed the daily equivalent of the maximum rate of pay for GS-15.
- (2) An agency may fix the pay of each committee staff member at a rate of the General Schedule, General Merit Schedule, or Senior Executive Service in which the staff member's position is appropriately placed (see Chapter 51 of Title 5 of the U.S. Code).
- (3) An agency may not fix the pay of a staff member at a rate higher than the daily equivalent of the maximum rate for GS-15, unless it has been determined by the CMO that the position would be appropriately placed at a higher grade under one of the above classification systems. Once such a determination has been made, the agency shall annually forward for review by the CMO documentation supporting the higher pay rate.
- (4) In establishing rates of compensation, the agency head shall comply with applicable statutes, regulations, and Executive Orders.

February 8, 1993

- (5) A staff member who is a Federal employee shall serve with the knowledge of the designated Federal official and approval of the employee's direct supervisor. If a non-Federal employee, the staff member shall be appointed in accordance with applicable agency procedures, following consultation with the committee.
- c Consultants. An agency shall fix the pay of a consultant to an advisory committee after giving consideration to the qualifications required of the consultant and the significance, scope, and technical complexity of the work. The rate of compensation may not exceed the daily equivalent of the maximum rate for GS-15.
- d Travel expenses. Committee members and staff members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by 5 U.S.C. 5703 for persons employed intermittently in Government service. Such payments for an alternate member of a committee shall be allowed only when the alternate member is attending a meeting in that capacity.
- e Special services. While performing committee duties, a committee member who is blind or deaf, or who qualifies as a disabled individual, may be provided services by a personal assistant for disabled employees if the member:
- (1) Qualifies as a disabled individual as defined by Section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794); and
 - (2) Does not otherwise qualify for assistance under 5 U.S.C. 3102 as an employee of an agency.

12 CLEARANCE OF COMMITTEE MEMBERS

- a Policy. A background clearance is required for all proposed committee members to be appointed by the Secretary, except those who are Federal employees.

February 8, 1993

DR 1041-1

b Procedure.

- (1) Four copies of Form AD-755, Advisory Committee Membership Background Information (Appendix G), shall be submitted to the Office of the Secretary for each proposed committee member. Clearance procedures will not be instituted if the biographical data is insufficient to permit a background review. In particular, any source of income in excess of \$10,000 during the preceding year (other than from the individual's primary employment), must be reported as a major source of income.
- (2) The above procedures shall be used for both existing and prospective members when an advisory committee's charter is being renewed or reestablished, whether or not biographical information had been submitted on the individual in the past.

13 APPOINTMENT OF MEMBERS

- a Authority. National and/or statutory committee members shall be appointed by the Secretary. Regional, State and local committee members shall be appointed by the agency official responsible for the committee unless determined otherwise by the CMO.
- b Invitation to serve on a national committee. Letters of invitation shall be prepared by the agency for the signature of the Secretary, and shall include:
 - (1) Purpose, objectives, and expected accomplishments of the committee;
 - (2) Name of the chairperson;
 - (3) Frequency of meetings, if known;

- (4) Location of meetings, if known;
- (5) Travel and per diem allowances, if applicable;
and
- (6) Expiration date of appointment.

The agency shall provide appropriate follow-up where a letter of invitation has been issued and no response is received within 21 days of the date the invitation was mailed.

c Certificates of appointment.

- (1) For national committees, Form AD-580, Certificate of Appointment, signed by the Secretary, shall be presented to each member (see Appendix H).
- (2) The certificates may be requisitioned from the Consolidated Forms and Publications Distribution Center. The agency shall arrange for presentation of the certificates either by mail at the time of appointment, or at the next meeting of the committee.

14 MEETINGS

a General. All committee meetings shall be subject to the following provisions.

- (1) No meeting shall be held except at the call of, or with the advance approval of, the designated Departmental official, and with an agenda approved by that official.
- (2) Committees shall meet under the chairpersonship of, or in the presence of, a designated Departmental official who shall have the authority and be required to adjourn any meeting whenever he/she considers adjournment to be in the public interest. No committee shall conduct a meeting in the absence of the Departmental official designated in the charter to chair or attend the meeting.

February 8, 1993

DR 1041-1

- (3) The Department shall maintain an open-door policy with respect to meetings. Meetings will be open to the public except when a determination is made by the Secretary, in writing, that any or all portions of a meeting should be closed in accordance with 5 U.S.C. 552b(c).
- (4) If an agency seeks to have all or part of a meeting closed on the basis of an exemption contained in 5 U.S.C. 552b(c), the agency shall prepare a determination for the Secretary's signature. The determination shall state that it is essential to close a portion(s) of the meeting and the specific reasons for this action. The determination shall be accompanied by an explanation of the reasons why the meeting should be closed. The determination and accompanying explanation shall be forwarded to the CMO, through OGC and OP, at least 45 days before the scheduled meeting.
- (5) The closing of a meeting or any portion of a meeting may be reviewed by the CMO after the meeting is held. If it is determined that a meeting or any portion thereof was closed inappropriately, corrective action may be taken.
- (6) Notice of all meetings, both open and closed, shall be published in the Federal Register at least 15, but no more than 45 calendar days prior to the meeting. Shorter notice may be authorized by the Secretariat for good cause or in emergency situations. The reasons for such emergency exceptions shall be made part of the meeting notice.
- (7) The agency shall be responsible for preparation of the notice and submitting it to the Federal Register through OGC. The agency shall start processing a meeting notice at least 45 days before the scheduled meeting date to allow for clearance within the Department and handling time at the Federal Register. The notice shall contain:
 - (a) The name of the advisory committee;

February 8, 1992

- (b) The time, date, place, and purpose of the meeting, including a summary of the agenda or the name of the person from whom it may be obtained;
 - (c) The extent to which the public will be permitted to attend or participate in the meeting;
 - (d) A statement that the meeting is open or, if the meeting is to be closed, an explanation of why it is closed; and
 - (e) The name and address of the person to whom written comments may be made.
- (8) A press release announcing a national committee meeting shall be prepared by the agency and forwarded to the Office of Public Affairs at least 15 days prior to the meeting. That Office will make the release available to the media. Releases announcing regional, State, and local committee meetings will be furnished by the agency to the local media.
- (9) With regard to an open or partially open meeting, the agency shall be responsible for the following:
- (a) The meeting shall be held at a reasonable time and at a place that is reasonably accessible to the public;
 - (b) The size of the meeting room shall be large enough to accommodate the committee members, the staff, and members of the public who could reasonably be expected to attend;
 - (c) Any member of the public shall be permitted to file a written statement with the committee before or within a reasonable time following the meeting; and
 - (d) Interested persons may be permitted by the committee chairperson to speak at the meeting in accordance with procedures established by the committee.

February 8, 1993

DR 1041-1

- (10) Detailed minutes shall be kept of all meetings. The chairperson or designated Department official shall certify the accuracy of the minutes, which shall include at least the following:
- (a) The time, date, and place of the meeting;
 - (b) A list of committee members, committee staff, and Department employees present;
 - (c) An accurate description of each matter discussed and the resolution, if any, made by the committee of such matter;
 - (d) Copies of all reports or other documents received, issued, or approved by the committee;
 - (e) A description of the extent to which the meeting was open to the public; and
 - (f) A description of public participation, including a list of members of the public who presented oral or written statements, and an estimate of the number who attended the meeting.
- (11) The records, reports, transcripts, working papers, etc., of all open committee meetings shall be available for public inspection and copying. If a portion of a meeting is closed, the minutes of the open portion shall be available to the public. If meetings are entirely or partially closed, the agency shall prepare at least annually a summary report of its activities and such related matters as would be informative to the public. No later than December 31, the agency shall prepare a Federal Register notice of availability of the report, including instructions which allow the public access to the report.
- (12) Committee records shall be maintained for the life of the committee and then disposed of in accordance with the agency's records disposal schedule.
- (13) If transcripts are made of a meeting, they shall be available within a reasonable period of time following the meeting.

February 9, 1993

- (14) Advice or recommendations of the committee shall be given only with respect to matters covered in the record of the committee's proceedings.
- (15) If, in lieu of a meeting, recommendations of committee members are solicited by mail or telephone, the agency shall publish a notice in the Federal Register, no later than the date the recommendations are sought. The notice shall fully describe the matter to be considered. The notice shall also include:
 - (a) Instructions to the public on how to file their views on the matter with the agency;
 - (b) A statement that the request and any responses received will be available for public inspection and copying; and
 - (c) The location where these records will be maintained.
- (16) A report for each committee where members' recommendations are solicited in this manner will be prepared at least annually by the agency. No later than December 31, the agency shall prepare a Federal Register notice of availability of this report, including instructions which allow the public access to the report.

15 DISCLOSURE OF OFFICIAL INFORMATION TO PUBLIC MEMBERS

Certain types of information classified under security regulations, or specifically restricted by law or Presidential directive, may not be disclosed to members of advisory committees. However, material otherwise restricted as "FOR OFFICIAL USE ONLY" may, in some circumstances, be made available when essential to the transaction of committee business. When making material available to committee members, it must be clearly understood that all material presented for review at an open meeting is available for public inspection and copying. Therefore, good judgment must be exercised to assure that presentation of information is essential and that risk of consequences adverse to the public interest has been carefully weighed.

February 8, 1993

DR 1041-1

16 REPORTING AND RECORDS

a External reporting requirements.

- (1) The Department shall submit a report on each advisory committee to the Secretariat in the manner and format required by the Secretariat, for preparation of the annual report required by the Act. Instructions and forms for preparing the report shall be issued by OP.
- (2) For each nonstatutory advisory committee, the Department shall submit an annual report to the appropriate committees of Congress and the Library of Congress as required by Title XVIII of the Food and Agriculture Act of 1977, as amended. Data for this report shall be prepared in accordance with guidelines furnished by OP.

b Reports issued by committees.

- (1) All reports and recommendations issued by a committee shall be in written form. The agency shall maintain copies of such reports and/or recommendations, and a written record of any responses made by the Department to the committee's recommendations.
- (2) When a report or recommendation is issued to the Secretary by a committee, the agency shall forward eight copies to the Library of Congress, Exchange and Gift Division, Federal Advisory Committee Desk, Washington, D.C. 20540. Excluded from this requirement are minutes of meetings, materials exempt under 5 U.S.C. 552b(c), reports prepared for submission to the Secretariat, and the report prepared in compliance with Title XVIII of the Food and Agriculture Act of 1977, as amended. Background papers prepared for the committee's use may also be provided to the Library of Congress, if deemed appropriate.

c Committee control system.

- (1) Each agency sponsoring a committee shall provide support services for that committee. The Secretary shall designate the agency that will provide support services for committees established or authorized by law.

- (2) The agency head shall designate an official to be responsible for maintaining central control records of all committees which the agency sponsors or for which it provides support services. The information shall be current at all times and agencies shall be prepared to furnish such information upon request.
- d Submission of Form AD-241, Committee Control Record.
- (1) Each agency, through its committee management official, must submit one copy of Form AD-241 (Appendix A) to OP within 15 days of the initial appointment of a new committee. Changes in members or related data must be reported on Form AD-241 within 15 days of the change.
 - (2) OP shall maintain this information in a data base for use in preparing the membership portion of the annual report referred to in Section 15a above.
- e Other records. In addition to Form AD-241, agencies shall maintain copies of the following:
- (1) Committee charter;
 - (2) Minutes of committee proceedings;
 - (3) Press releases and committee reports;
 - (4) Secretarial determinations under 5 U.S.C. 552b(c) that committee activities will be closed to the public; and
 - (5) Any other working papers properly a part of committee or subcommittee records.
- f Financial recordkeeping and reporting.
- (1) Funds for non-Forest Service committees are included in the Departmental Administration budget and are allocated by the CMO to the appropriate Under or Assistant Secretary. That official is responsible for distributing funds to the agencies within his/her jurisdiction that sponsor committees.

February 8, 1993

DR 1041-1

- (2) Committee expenses shall not exceed the estimate in the charter by the greater of \$500 or 10 percent, without prior approval of the CMO. Agencies shall request approval by sending a written justification to the CMO through OP.
- (3) Each agency, through the responsible official, shall maintain up-to-date records that disclose the disposition of funds made available to its advisory committees. The records shall be available for inspection and audit by the Department and/or the General Accounting Office.
- (4) Agencies shall report amounts expended to OFM in accordance with instructions from that Office.

Indicates Chairperson of Committee
 * I/A-American Indian/Alaskan Native; A-Asian or Pacific Islander; B-Black; H-Hispanic; W-White.
 (Continue on reverse)
 AD-241 (3/24/92)

February 5, 1993

APPENDIX A

4. Membership (continued)	--Member's Full Name; --title; --Income sources from other than primary employment	Employer (or) Organization	Mailing Address: Street or P.O. Box City, State, ZIP Code	* Appointment Add/Drop Date	Ethnic Code**

AD-241 (3/24/92)

DR 1041-1

February 8, 1993

APPENDIX C
U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

DEPARTMENTAL REGULATION		NUMBER 1042-20
SUBJECT: Mono Basin National Forest Area Advisory Board	DATE: July 16, 1992	
	OFF: Forest Service	

1 PURPOSE/SCOPE

- a The Mono Basin National Forest Scenic Area Advisory Board (hereinafter referred to as the "Board") was established by section 306 of the California Wilderness Act of 1984 (Pub. L. No. 98-425). This regulation serves as the Charter for the Board.
- b The purpose of this Board is to advise the Secretary on:
 - (1) The administration policies, programs, and activities affecting the the Scenic Area.
 - (2) Preparation and implementation of the management plan.
 - (3) The location of the visitor center.

2 SPECIAL INSTRUCTIONS/CANCELLATION

- a The Board shall terminate on May 22, 1995.
- b This regulation will expire 2 years from the date of signing.
- c DR 1042-80 dated April 16, 1990, is hereby superseded.

3 MEMBERSHIP AND OFFICERS

- a The Board shall be composed of nine members.
- b Members will be appointed as follows:
 - (1) Five members by the Mono County Board of Supervisors,
 - (2) Two members by the Governor of California (one of whom shall be an employee of the California Department of Parks and Recreation),
 - (3) One member by the Mayor of Los Angeles, and

DISTRIBUTION

C-1

February 8, 1993

DR 1041-1
APPENDIX C

- (4) One member by the Secretary (who shall be an employee of the Forest Service).
- c Each member shall be appointed for a term of 3 years.
- d The Chairperson of the Board shall be elected by members.
- e The Forest Service member shall serve as the designated Federal official under sections 10(e) and 10(f) of the Federal Advisory Committee Act (5 U.S.C. App.)
- f A majority of Board members shall constitute a quorum for the conduct of all business of the Board.
- g Any vacancy on the Board shall be filled in the same manner in which the original appointment was made.
- h Equal opportunity practices, in line with USDA policies, will be followed in all appointments to the Board. To ensure that the recommendations of the Board have taken into account the needs of the diverse groups served by the Department, membership should include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

4 DUTIES

Members shall consider broad questions of management of the Scenic Area, as mentioned in section 1(b) of this regulation, and advise or make recommendations to the designee for the Secretary at meetings called by the Forest Service member. The designee is the Regional Forester, Pacific Southwest Region, San Francisco, California.

5 ESTIMATED ANNUAL OPERATING EXPENSES

- a Members shall serve without compensation, but may receive reimbursement for travel expenses and per diem in accordance with USDA travel regulations for attendance at Board functions.

February 8, 1993

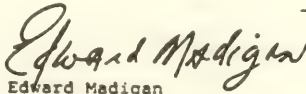
- b Estimated annual operating costs are \$5,000 and .10 staff years of support.

6 NUMBER AND FREQUENCY OF MEETINGS

The Board shall meet at least annually, with other meetings held at the call of the Forest Service member, as needed. All meetings will be open to the public.

7 REPORTS/SUPPORT

- a The Board reports to the Secretary of Agriculture through Forest Service and Departmental channels.
- b The Forest Service will provide support for the Board.


Edward Madigan
Secretary

APPENDIX D

7804

Notices

Federal Register

Vol. 57, No. 64

Thursday, March 5, 1992

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Radio and Television Broadcast Use Fee Advisory Committee: Establishment and Nominations

AGENCY: Office of the Secretary, USDA

ACTION: Notice request for nominations and comments

SUMMARY: In response to the Conference Report accompanying the Fiscal Year 1992 Appropriations Act, the Secretaries of Agriculture and of the Interior have agreed to establish an advisory committee to review and report on how to establish rental fees for radio and television broadcast uses which are authorized on National Forest System and public lands. The committee would be established for a 6-month period and report its findings. Nominations to serve on the committee and comments on categories of membership and duties of the committee are requested.

DATES: Nominations for membership on the Committee and comments must be received in writing by March 20, 1992.

ADDRESSES: Send nominations for membership on the Committee and comments to Cy Jamison (WO320), Director, Bureau of Land Management, USDL 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Brent Handley, Lands Staff, Forest Service, USDA (202) 205-1264, or Dave Cavanaugh, Lands and Realty Branch, Bureau of Land Management, USDL (202) 206-5441.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (5 U.S.C. appendix), notice is hereby given that the Secretaries of Agriculture and the Interior intend to establish the Radio and Television Broadcast Use Fee Advisory Committee, hereafter referred to as Committee. The purpose of this Committee is to advise the Secretaries of Agriculture and the Interior on appropriate methods of determining fair market value for radio and television broadcast uses authorized on lands managed by the Forest Service and Bureau of Land Management.

The Secretaries have determined that the work of the Committee is in the public interest and relevant to the duties of the Department of Agriculture and Department of the Interior. The duties include the management of communications site uses on National Forest System and public lands, under the provisions of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 et seq.). No other advisory committee or agency of the Department of Agriculture or Department of the Interior is performing the tasks that will be assigned to the Committee.

The Committee, including the Chair, shall consist of 9 members as follows:

1. One member representing each of the following:
 - a. Radio and television broadcasters authorized to use lands administered by the Forest Service or Bureau of Land Management;
 - b. Radio or television broadcasters who primary broadcast facilities are located on leased private lands;
 - c. Radio or television translators;
 - d. State, County or local governments;
 - e. Managers of communications sites;
 - f. Individual or representatives of an organization knowledgeable of methodologies for determining market value;
 - g. Public other than the individuals or groups mentioned above.
 2. A representative of the USDA, and
 3. A representative of the USDL.
- Members appointed to the Committee shall be qualified to provide input and data necessary to contribute to the

purpose and duties of the Committee. Persons with experience and knowledge in the methods of determining fair market value will be given preference for appointment. A member of the Lands Staff, USDA Forest Service, will serve as the Executive Secretary of the Committee.

The duties of the Committee are to: (1) Review and report on the use of appraisals to establish fair market rental fees for radio and television broadcast uses on lands administered by the Forest Service and Bureau of Land Management; (2) review and report on reasonable options for establishing fair market rental fees for radio and television broadcast uses; and (3) to review and report on the appropriateness of waivers or reductions in rental fees for radio and television broadcast uses based on requirements for licensing under the Communications Act of 1934 and within the authority of the Federal Land Policy and Management Act of 1976.

The Secretaries invited those individuals, organizations and interest groups affiliated with the categories listed above to nominate individuals for membership on the Committee. Nominations should describe and document the proposed member's qualifications for membership to the Committee. The Secretaries seek a diverse group of members representing a broad spectrum of persons interested in the management of National Forest System and public lands.

Equal opportunity practices will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDL and USDA, membership should include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Done in Washington, DC, this 28th day of February, 1992.

Charles R. Hilty,

Assistant Secretary for Administration

[FR Doc. 92-5117 Filed 3-4-92; 8:45 am]
BILLING CODE 5410-11-6

CG 1041-1

February 8, 1993

AD-116 (1961)

Secretary's Correspondence Jacket

TO APPENDIX E

DATE _____ "CHECKING" _____

FILE DESIGNATION _____

INSTRUCTIONS

This jacket is for use in covering a letter prepared by a USDA agency for signature in the Office of the Secretary.

Follow procedures outlined in the U.S. Government Correspondence Manual, as supplemented by USDA instructions.

Answer all correspondence within prescribed time limits.

If this jacket carries a number preceded by the designation "SEC," route it through or call the Secretary's Records Section, ext. 3337, when passing it to another agency.

SUMMARY

80

REF. (1)	DATE	REF. (2)	DATE
REF. (2)	DATE	REF. (3)	DATE
REF. (3)	DATE	REF. (4)	DATE
AGENCY ACKNOWLEDGMENT ()		INTERIM REPLY ()	
		FINAL COPY ()	

INTERIM REPLY PREPARED IN (Agency):

DIVISION OR OFFICE

DICTATED BY

DATE

FINAL REPLY PREPARED IN (Agency):

DIVISION OR OFFICE

DICTATED BY

DATE

IF THE LETTER IS REWRITTEN IN OTHER THAN THE PREPARING AGENCY, THE REWRITING AGENCY SHALL

(a) Type on all copies of the redrafted letter the name of the originating agency and the initials of the original dictator.

(b) Place the canceled salmon copy of the original draft beneath the salmon copy of the rewritten letter.

(c) Furnish the following information:

WRITTEN IN (Agency):

DIVISION OR OFFICE

DICTATED BY

DATE

REMARKS - SPECIAL INSTRUCTIONS:

	SENT TO	DATE	SENT TO	DATE
1			8	
2			9	
3			10	
4			11	
5			12	
			13	
			14	

PRIORITY - HANDLE PROMPTLY

DR 1041-1

APPENDIX F

February 8, 1997

AD116**CLEARANCE AND APPROVAL FOR DEPARTMENTAL ISSUANCES
UNITED STATES DEPARTMENT OF AGRICULTURE**

1	TYPE OF CLEARANCE/ ACTION	Simultaneous <input type="checkbox"/>	Sequential <input type="checkbox"/>	New <input type="checkbox"/>	Revised <input type="checkbox"/>	Amended <input type="checkbox"/>		
2	CLASSIFICATION NUMBER AND TITLE							
3	INDEX TERMS							
4	ORIGINATOR	Name	Room Number	Extension	Date	OPI		
5	FORMS AND REPORTS CLEARANCE	Forms	Date	Reports	Date			
6	CLEARANCE DEADLINE / DISTRIBUTION	Complete by (date)		Distribution Codes				
7	CLEARANCE ORIGINATING ORGANIZATION	Name	Title	Room Number	Date In Out		Initials	
8	OTHER CLEARANCES See specific instructions on reverse	Organization Abbreviations	Name and Title	Room Number	Date In Out		Concur no comments attached	Nonconcur comments attached
9	REMARKS (for additional space attach paper)							
10	SIGNATURE AUTHORITY	Signature	Title			Date		

February 8, 1993

DR 10-1-1
APPENDIX F

Writer's Readability Appraisal

1 GENERAL INSTRUCTIONS	Prepare original and allow one copy for each clearance officer if clearances are obtained simultaneously. If clearance is obtained sequentially, only one copy is required.																																		
2 SPECIFIC INSTRUCTIONS <small>Clearance officers are to indicate concurrence or nonconcurrence by initialing one of the three columns described</small>	<p>a. Concur (No Comments)—In agreement with the directive to the extent that it affects the functions and activities of the clearing organization.</p> <p>b. Concur (Comments Attached)—The clearing organization is in general agreement with the directive but is suggesting some changes. These changes, however, are only suggestions and the directive is considered acceptable if the changes are not made. If clearance is simultaneous, minor changes may be entered on the directive itself. If major changes are suggested, the clearance office must prepare a memorandum and return it with the directive to the originator. If clearance is sequential, the clearance officer should contact the OPI to resolve any conflicts before forwarding to the next clearance officer.</p> <p>c. Nonconcur (Comments Attached)—The clearing organization has strong feelings about the effects of the proposed directive on its own areas of responsibilities and operations. The nonconcurring official must prepare a memorandum explaining the reasons for nonconcurrence and stating what specific changes are necessary before concurrence can be given. This memorandum of nonconcurrence is attached to the directive package and returned to the originator immediately for both simultaneous and sequential clearances.</p>																																		
3 INSTRUCTIONS FOR FOG INDEX	Choose a representative sample of text of at least 100 words. For long directives, use samples from several pages. Analyze short documents (one-half page or less) completely. Exclude tables, graphics, and lists of one- or two-word items.																																		
4 ENTER DATA FOR EACH SAMPLE AS INDICATED BELOW	a. Identify Sample	<table border="1"> <thead> <tr> <th colspan="5">Page and paragraph number of sample(s)</th> <th>Total</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>				Page and paragraph number of sample(s)					Total																								
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	b. Number of Words <small>(Do not count words in headings unless continuous with text. Treat as one word hyphenated words, numbers, abbreviations, and other symbols.)</small>	<table border="1"> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>																																	
	c. Number of Sentences <small>(Count units which end in a period or a question mark. In vertical listings (except one- or two-word items) count the introduction and each item as a separate sentence.)</small>	<table border="1"> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>																																	
	d. Number of Hard Words <small>(Treat hard words, all words of 3 or more syllables, abbreviations and symbols. Do not include capitalized words (proper nouns, adjectives, titles), unless symbolized or abbreviated.)</small>	<table border="1"> <tbody> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>																																	
5 DETERMINE THE AVERAGE FOG INDEX FOR ALL TEXT USING TOTALS IN ITEM 4 ABOVE	<p>a. Average number of words per sentence (Item 4b divided by item 4c)</p> <p>b. Percent of hard words (Item 4d divided by item 4b)</p> <p>c. Sum of word average and hard word percent (Item 5a plus Item 5b)</p> <p>d. Fog index (Item 5c multiplied by .4)</p>																																		
6 HOW YOU CAN LOWER THE FOG INDEX	<p>a. Use simple words</p> <p>b. Write in the active voice</p> <p>c. Write short sentences</p> <p>d. Limit sentences to one thought</p> <p>e. Cut useless words and information</p>																																		

The above procedure is based on Robert Gunning's Fog Index Formula from "The Technique of Clear Writing" McGraw-Hill Book Co., Inc.

DR 1541-1

February 2, 1993

Form Approved OMB
No. 0505-0001
Expires: 8/31/95

APPENDIX G

United States Department of Agriculture

ADVISORY COMMITTEE MEMBERSHIP BACKGROUND INFORMATION

Privacy Act Notice

Public Laws 95-113 and 93-579 permit collection of the data requested on this form. The information is used to determine qualifications, suitability and availability for service on advisory committees. The information will be used to conduct background clearances and/or for annual reports on advisory committees. Failure to submit this information may result in nonselection of a prospective advisory committee member or termination of the committee.

1 Name (Last, First, Middle)	2 Social Security Number
3 Residence Address (include ZIP Code)	4 Telephone Home Office FAX
5 Place of Birth	6 Date of Birth
7 Name of Employer	
8 Employer Address (include ZIP Code)	9 Your Occupation/Title
10 List your business experience	
11 List education and any specialized experience	

(Continued on reverse)

Form AD-755 E 11-92

February, 1980

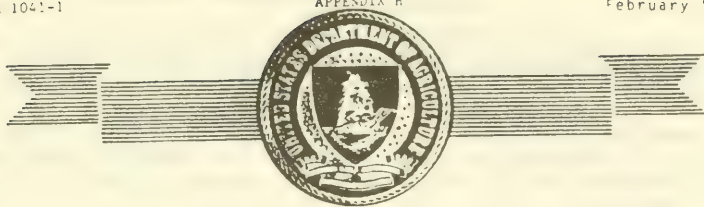
APPENDIX G

12. If applicable, how long have you been engaged in farming or production, and what is the size of your farming operation (i.e., list acreage and pounds produced by kind of crop, as well as kinds and numbers of livestock)?
-
13. List producer or farm organizations (include whether a member or officer and how long affiliated).
-
14. List other affiliations and/or service as a community leader that would benefit you in your role as a member of the advisory committee.
-
15. List any Federal advisory committee or board on which you are currently a member and the number of years you have served on that committee or board.
-
16. List sources of income—in excess of \$10,000—for the past calendar year from other than your primary employment. List only sources; do not show amounts of income from each source.
-
-
-
17. Have you ever been convicted of a felony? (A felony is defined as any violation of law punishable by imprisonment of longer than one year.) If so, please explain.
-
18. As a result of your participation in Federal programs, have any judgments been rendered against you? As a result of participation in any governmental programs relative to the purposes of the advisory committee for which you are a nominee, have any civil or criminal actions been initiated against you? If so, please explain.
-

Signature

Date

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250, and to the Office of Management and Budget, Paperwork Reduction Project (OMB No. 0505-0001), Washington, D.C. 20503.



Certificate
of Appointment
presented to

*With appreciation for accepting the call
to serve the Nation and the
United States Department of Agriculture
as a member of the*

DATE

SECRETARY OF AGRICULTURE

U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C. 20250

DEPARTMENTAL REGULATION		NUMBER: 1043-28
SUBJECT: National Advisory Committee on Microbio- logical Criteria for Foods	DATE: May 24, 1994	
	OPI: Food Safety and Inspection Service	

1 PURPOSE

- a The Secretary, after consultation with the Secretary of Health and Human Services on the need for a joint Agriculture/ Health and Human Services advisory committee, hereby renews the National Advisory Committee on Microbiological Criteria for Foods. The Committee was initially established by the Secretary of Agriculture (USDA) on March 18, 1988.
- b The purpose of the Committee is to provide advice and recommendations on the development of microbiological criteria for foods.
- c The functions of this Committee cannot be performed in less than 2 years, and renewal is considered in the public interest in connection with the duties and responsibilities of both Departments in assuring the safety and wholesomeness of foods.
- d The work of the Committee may be accomplished through subcommittees consisting of members from the whole Committee.

2 SPECIAL INSTRUCTIONS

- a This regulation will expire 2 years from the date of this regulation, unless the Secretary determines prior to that date that renewal is in the public interest.
- b Departmental Regulation Number 1043-28 dated April 16, 1992, is hereby superseded.
- c This document will also serve as the charter for the National Advisory Committee on Microbiological Criteria for Foods.

3 OFFICERS AND MEMBERSHIP

- a The Assistant Secretary for Marketing and Inspection Services, or designee, will serve as the Chairperson. The Commissioner of the Food and Drug Administration, or designee, will serve as the Vice Chairperson. A representative of the Food Safety and Inspection Service will serve as the Executive Secretary.
- b The membership of the Committee will be appointed by the Secretary of Agriculture after consultation with the Secretary of Health and Human Services (HHS). Because of their interest in the microbiological criteria of food, advice on membership appointments will be requested from the Department of Commerce's National Marine Fisheries Service (NMFS) and the Department of Defense's U.S. Army Natick Research and Development Center (Natick). Membership will consist of not more than 25 individuals with expertise in food science, microbiology and other relevant disciplines. Members will serve at the discretion of the Secretary.
- c Equal opportunity practices, in line with USDA policies, will be followed in all appointments to the Committee. To ensure that the recommendations of the Committee have taken into account the needs of the diverse groups served by USDA, membership should include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

4 DUTIES

The Committee will provide advice and recommendations to the Secretaries on the development of microbiological criteria by which the safety and wholesomeness of food can be assessed, including criteria for microorganisms that indicate whether foods have been processed using good manufacturing practices.

5 ESTIMATED ANNUAL OPERATING COSTS

- a Members serve without pay, but with reimbursement of travel expenses and per diem for attendance at Committee or subcommittee meetings called by the Chairperson.
- b Annual operating costs are estimated to be \$200,000 and will be divided among USDA, HHS, NMFS, and Natick. Staff year requirements are estimated to be 2.

6 NUMBER AND FREQUENCY OF MEETINGS

The full Committee is expected to meet semiannually and the subcommittees will meet as deemed necessary by the Chairperson.

7 REPORTS AND SUPPORT

- a The Committee reports to the Secretary of Agriculture through the Assistant Secretary for Marketing and Inspection Services and to the Secretary of Health and Human Services through the Assistant Secretary for Health.
- b The Food Safety and Inspection Service will provide administrative staff support to the Committee.



MIKE ESPY
SECRETARY

**National Advisory Committee on
Microbiological Criteria for Foods**

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**MEMBERS WHOSE TERMS EXPIRE IN
 1994 IN BOLD.**

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio

Bernard Sanders, Vermont
Independent

Majority (202) 225-2548

FAX (202) 225-2382

Minority (202) 225-2738

June 30, 1994

Mr. Henry J. Voss
Secretary
California Department of Food
and Agriculture
1220 N Street
Sacramento, CA 94271-0001

Dear Mr. Voss:

Thank you for appearing before the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations, on June 16, 1994, and testifying on "Fresh vs. Frozen Chickens and Other Issues Involving the U.S. Department of Agriculture's (USDA) Regulation of Poultry Products."

The subcommittees found your testimony about the California Fresh Poultry Consumer Protection Act to be informative and highly engaging. Your testimony will be an invaluable resource in the subcommittees' evaluation of the USDA's policy on the labeling of "fresh" chicken.

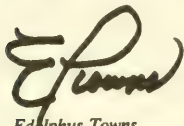
During the hearing you agreed to provide additional information for the record. We would appreciate receiving your written responses to the following questions by Friday, July 15, 1994:

- (1) Has your department estimated the amount of consumer dollars spent in California on poultry labeled as "fresh" under USDA's regulations that was frozen between 26 and 0 degrees Fahrenheit? What is the magnitude of the problem in consumer dollars in California?*
- (2) What is the amount of frozen chicken and fresh chicken produced in California and what is the amount of frozen chicken and fresh chicken produced outside California? Of the latter amount, how much is shipped to and distributed in California?*

Mr. Voss
June 30, 1994
Page Two

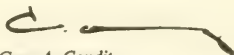
Let us assure you that the subcommittees will continue to oversee USDA's efforts to reexamine its current labeling policy.

Again, thank you very much. If you have any questions regarding the additional questions please contact Bill Layden of the subcommittee staff at 202/225-2548.



Edolphus Towns
Chairman
Human Resources and
Intergovernmental Relations
Subcommittee

Sincerely,



Gary A. Condit
Chairman
Information, Justice,
Transportation, and
Agriculture Subcommittee

DEPARTMENT OF FOOD AND AGRICULTURE

1220 N Street, Room A-114
P. O. Box 942871
Sacramento, CA 94271-0001



July 14, 1994

Congressman Edolphus Towns, Chairman
Human Resources and Intergovernmental
Relations Subcommittee of the Committee
on Government Operations and
Congressman Gary A. Condit, Chairman
Information, Justice, Transportation, and
Agriculture Subcommittee
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressmen Towns and Condit:

In response to your request for additional information following the recent hearing in Washington, D.C. on "Fresh vs. Frozen Chickens and Other Issues Involving the United States Department of Agriculture's (USDA) Regulation of Poultry Products", we are providing the information contained herein for the record.

It is estimated that Californians spend more than \$407 million on poultry sold as "fresh" that was previously frozen between 26 and 0 degrees Fahrenheit and then thawed for retail sale. Based on a conservative estimate of an additional \$.10 per pound for the purportedly "fresh" product, California consumers would be paying an additional \$50 million annually. The actual amount may be far higher.

California companies produce about 450 million pounds of fresh poultry for retail sale within the State. Since the amount of frozen product sold is so low, there are no accurate figures regarding the State's production of frozen product.

However, out-of-state companies produce about 173 million pounds of frozen poultry and more than 11 billion pounds of poultry that is not "frozen" under current federal standards (poultry above 0 degrees Fahrenheit). These out-of-state companies sell approximately 510 million pounds of poultry frozen between 0 and 26 degrees Fahrenheit in California -- poultry that is often labeled "fresh" in the absence of any federal regulation to prevent such deception.

Congressmen Edolphus Towns and

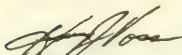
Gary A. Condit

July 14, 1994

Page Two

We hope you share our concern regarding the negative economic impact that this ongoing labeling deception has on the consumer. Of course, this is not a problem limited to Californians, but is shared by consumers throughout the country who are currently deprived of the right to know whether the purportedly fresh poultry they buy has ever been previously frozen. Thank you for availing us of the opportunity to address this important issue.

Sincerely,



Henry J. Voss

Secretary

(916) 654-0433

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee

of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515
July 6, 1994

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio
Bernard Sanders, Vermont
Independent

Majority (202) 225-2548
FAX (202) 225-2362
Minority (202) 225-2798

The Honorable Mike Espy
Secretary of Agriculture
U.S. Department of Agriculture
Fourteenth Street and Independence Ave., S.W.
Washington, DC 20250

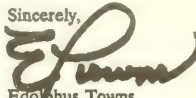
Dear Mr. Secretary:

As you are aware, in the exercise of its oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Human Resources and Intergovernmental Relations and the Information, Justice, Transportation, and Agriculture Subcommittees of the House Committee on Government Operations jointly conducted a hearing on June 16, 1994, on the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. At the hearing, Mr. Richard Rominger, Deputy Secretary, agreed to respond to additional questions submitted in writing by members of the subcommittees. This letter conveys these additional questions and requests for information (see attached) except for one request from Rep. John Mica that we have addressed in separate correspondence to you. The subcommittee would appreciate receiving the answers and requested information by Wednesday, July 20, 1994.

In addition, the subcommittee has not yet received an updated report on USDA's pathogen reduction activities and the status of each of your initiatives as Mr. Rominger asked to submit for the record on page 11 of his written statement. I would appreciate receiving this updated information also by July 20, 1994.

Thank you in advance for your cooperation. Please contact Bill Layden of the subcommittee staff at (202) 225-2548 if you have any questions.

Sincerely,



Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

cc: The Honorable Steven Schiff
(Ranking Minority Member)

Attachment

Action Office: fsis
Referral Code: 35



* 3 0 6 1 1 2 9 *

ATTACHMENT

ATTACHMENT

ADDITIONAL QUESTIONS FOR THE RECORDRep. Towns

1. In an October 12, 1988, memorandum from Ashland Clemons, Acting Director, Standards and Labeling Division, to Margaret O'K. Glavin, Acting Assistant Deputy Administrator, Technical Services, Mr. Clemons wrote, "Therefore, the 26° F temperature appears to be very soundly based and is, in fact, another very generous accommodation towards the industries needs, both from a safety and esthetics perspective." What did Mr. Clemons mean by the phrase, "another very generous accommodation towards the industries needs?" What other "generous accommodations" has USDA made for the poultry industry?
2. On February 10, 1994, Agriculture Secretary Espy announced that he had directed USDA to reexamine its policy for use of the term "fresh" on poultry product labels. What do USDA's regulations and policy guidelines provide for use of the term "fresh" on meat and other non-poultry products? Does USDA plan to reexamine the use of the term "fresh" on meat and other non-poultry products? Why or why not?
3. What does the "sell by date" mean on packaged poultry products? What USDA regulations and policies govern this date? Does USDA review and approve these dates? What scientific data exists to support the determination of these dates? How does USDA ensure compliance with these dates?
4. In the wake of the E. coli 0157:H7 outbreak Agriculture Secretary Espy testified before a Senate panel in February 1993 on the need for additional legislative authority. In November 1993, former Assistant Secretary Eugene Branstool testified before this subcommittee that USDA was preparing a legislative package to increase its ability to trace-back the source of pathogens and control their presence on meat and poultry products. What is the status of this legislative package and why has it taken so long to develop and submit to the Congress?
5. According to a March 25, 1994, Reply Brief of Amicus Curiae United States, that USDA had previously submitted to the subcommittees, USDA has advanced its interpretation of the Poultry Product Inspection Act's (PPIA) preemption clause as an amicus curiae in Istituto Puertorriqueno de Carres, Inc. v. Davila, Civil No. 92-2098 (HL) (D.P.R. 1992). The Reply Brief also indicates that this case was settled before resolution. What is USDA's understanding of this settlement? Please provide a copy of the amicus curiae brief and copies of all correspondence between USDA and Puerto Rico from March 1988 through the present concerning the PPIA's preemption clause.
6. According to the written statement of Mr. Richard Rominger, Deputy Secretary of

Agriculture, the Food Safety Inspection Service (FSIS) has reexamined its use of the USDA official inspection legend, "Inspected for Wholesomeness," which appears on Federally inspected poultry products. According to Mr. Rominger, the legend or seal "does not represent that the poultry product is sterile and completely free of pathogens." His statement also says that USDA will design its regulatory programs "through careful and deliberate consideration of the needs and expectations of the consumer, as well as the views of other interested parties, and consistent with sound scientific principles."

- What specifically did FSIS do to "reexamine" its use of the official inspection legend? Did USDA conduct any consumer surveys or collect other data to determine consumer understanding and expectations about the legend? If yes, please provide a copy of these data, analyses and reports.
 - What data does USDA have on consumers' understanding and expectations of the "Wholesomeness" seal? What data does USDA have to establish that consumers know and understand that its official inspection legend "does not represent that the poultry product is sterile and completely free of pathogens?" Please provide copies of all such data.
7. What is the legal status of FSIS Policy Memoranda? What requirements exist regarding the development and implementation of policy memoranda, including contacts with members of the regulated industry and development of a supporting administrative record? Please provide a complete inventory of all operational FSIS Policy Memoranda.
 8. What is the status of the USDA/FSIS Technical Advisory Group (TAG) on risk assessment? Has the group been dissolved or has its work been impaired in any way and, if yes, why?
 9. Will the poultry enhancement program include microbial guidelines and testing requirements on raw product? Please explain.
 10. Please provide a copy of USDA's proposed rule for mechanically separated red meat and advance notice of proposed rulemaking for mechanically deboned poultry products.
 11. To what extent do differences in USDA's regulations on carcass chilling procedures favor poultry over red meat? What evidence exists to show "that poultry producers have pushed chilling technology in the direction of ensuring the maximum allowable water gain instead of in the direction of reducing water gain" as indicated in the draft memorandum from H. Russell Cross, former Administrator, FSIS, to Eugene Branstool, former Assistant Secretary, Marketing and Inspection Services that was provided to the subcommittee? What is the status of FSIS's reevaluation of policies and practices in both red meat and

poultry regarding carcass chilling and when will this activity be concluded?

12. What were the major findings of the Research Triangle Institute study on permitted exemption practices and what is the status of FSIS's review of this study? Please provide copies of the study and FSIS's review and analysis of it.

Rep. Condit

1. What are the USDA's, or FSIS's, guidelines on meeting with industry officials concerning matters that are pending regulation? Are employees required to keep any type of logs, files, memoranda, etc.?
2. Do any of the guidelines from above apply to matters that are to be decided through the use of a "policy memo?" Are there any separate guidelines concerning industry contacts during the formulation of a policy memo?
3. Is it the FSIS's opinion that it does not in any way regulate the information printed upon boxes of poultry product that are delivered to the retailer. Specifically, the picture of the Tyson shipping box placed into the hearing record indicated that "the freezing point of poultry is 28-32 degrees." This information actually contradicts the spirit, if not the letter, of Policy Memo 022C. Is it the FSIS position that this information is correct or incorrect. If it is incorrect, is it beyond the scope of FSIS to order a change in the message?
4. Was the issue of fresh vs. frozen in any way considered during the deliberations that led to the new nutrition labeling or safe handling and cooking labeling on raw products that will take effect on July 6, 1994. If so, specifically what criteria were used?
5. Please supply the Subcommittee with a list of the scientific literature produced since January 1, 1990 that has been reviewed as part of the "reevaluation" of fresh labels on poultry.

Rep. Schiff

1. Please provide a copy of all written ethical guidelines for employees at the U.S. Department of Agriculture to each Member of the two subcommittees.

Rep. Thurman

1. Please provide the toll-free number for USDA's meat and poultry hot-line and information on the hot-line to disseminate to constituents, especially information on consumer guidelines for refreezing poultry products.

Rep. Horn

1. According to the written statement from Henry J. Voss, Secretary, California Department of Food and Agriculture, several states other than California have enacted laws that deviate from Federal standards but USDA has not gone to court to challenge these other states. What other state laws deviate from USDA's meat and poultry statutes and regulations and what has USDA done or attempted to do about these deviations?
2. Please provide curricula vitae for the three USDA witnesses that appeared before the Subcommittees: Mr. Richard Rominger, Deputy Secretary; Mr. Terry Medley, Acting Administrator, FSIS; and Mr. John Golden, Associate General Counsel for Regulatory and Marketing.



DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

In response to your letter of July 6, 1994, the Department of Agriculture (USDA) provided certain information answering your questions on USDA's policies regarding the labeling of poultry as "fresh," USDA's inspection seal, a comparison of meat and poultry regulations, and differences in State and Federal laws regulating meat and poultry products. I regret that a letter of transmittal was not included with the package.

The information previously provided was obtained from various offices within the Food Safety and Inspection Service (FSIS), including: the Deputy Administrator for Regulatory Programs; the Product Assessment Division ("fresh" material); the Deputy Administrator for Administrative Management; the Personnel Division (employee status); the Policy Evaluation and Planning Staff; the Freedom of Information Act Office; the Policy Analysis and Evaluation Office (policy memoranda); the Deputy Administrator for Inspection Operations; the Resources Management Staff (meat and poultry inspection operations); and the Federal/State Relations Staff (correspondence between Puerto Rico and USDA). Outside FSIS, additional information on guidelines for rulemaking was obtained from USDA's Office of General Counsel.

If you have any questions, please contact Ms. Patricia Jensen, Acting Assistant Secretary for Marketing and Inspection Services, at (202) 720-4256.

Sincerely,

A handwritten signature in cursive script, appearing to read "Rick Rominger".

RICHARD ROMINGER
Deputy Secretary

cc: Honorable Steven Schiff

Towns Q.1 -- In an October 12, 1988, memorandum from Ashland Clemons, Acting Director, Standards and Labeling Division, to Margaret O'K. Glavin, Acting Assistant Deputy Administrator, Technical Services, Mr. Clemons wrote, "Therefore, the 26 degree Fahrenheit temperature appears to be very soundly based and is, in fact, another very generous accommodation towards the industry's needs, both from a safety and esthetics perspective." What did Mr. Clemons mean by the phrase, "another very generous accommodation towards the industry's needs?" What other "generous accommodations" has USDA made for the poultry industry?

The memorandum quoted in your question was written in 1988, during a previous administration, by an individual who retired as Director of the FSIS Food Labeling Division on July 10, 1993. It is not clear what Mr. Clemons meant by the quoted phrase. Rather than speculating as to its meaning, the Department respectfully suggests that the Committee contact Mr. Clemons directly to determine what he meant by the phrase.

Under this Administration, Secretary Espy has insisted upon equal treatment of industries regulated by the Department. The Department's decisions in the areas of food safety and the regulation of the meat and poultry industries are based on sound, scientific principles. The Secretary has also worked to ensure that all interested parties, including consumers, are provided the opportunity to present their views on issues before the Department.

Towns Q.2 -- On February 10, 1994, Agriculture Secretary Espy announced that he had directed USDA to reexamine its policy for use of the term "fresh" on poultry product labels. What do USDA's regulations and policy guidelines provide for use of the term "fresh" on meat and other non-poultry products? Does USDA plan to reexamine the use of the term "fresh" on meat and other non-poultry products? Why or why not?

The Federal meat inspection regulations in 9 C.F.R. 317.8(b)(6) state that "fresh" cannot be used on the labels of cured meat products, i.e., those that contain any sodium nitrate, sodium nitrite, potassium nitrate, or potassium nitrite, or to which salt has been added for preservation.

Further explanation on the use of the term "fresh" may be found in Policy Memorandum 022C. Policy Memo 022C states that the word "fresh" may not be used in conjunction with the product name of: (1) any cured product, e.g., corned beef, smoked cured turkey, and prosciutto, (2) any canned, hermetically sealed shelf stable, dried, or chemically preserved product, and (3) any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit.

The Department does not plan to reexamine the use of "fresh" on labels of meat and other non-poultry products because no issues have been raised regarding the use of "fresh" on the labels of these products.

Towns Q.3 – What does the "sell by date" mean on packaged poultry products? What USDA regulations and policies govern this date? Does USDA review and approve these dates? What scientific data exists to support the determination of these dates? How does USDA ensure compliance with these dates?

The "sell-by" date is one of the many quality descriptions used by industry to convey the meaning of a calendar date that may appear on the labels of meat or poultry products. USDA regulations permit, but do not require, the designation on meat product labels of information on the packaging date of the product or the shelf life of the product. However, if a date is used, 9 C.F.R. Part 317.8(b)(32) requires that it must be explained in terms such as "packing" date, "sell-by" date, or "use before" date. Any additional qualifiers, such as "for maximum freshness" or "for best quality" must be submitted to the agency as part of the prior label approval process. In addition, the product is inspected at the time it is packaged to ensure that product is not adulterated or misbranded.

USDA's poultry regulations, similarly, do not require that packaging or shelf life dates appear on poultry product labels. The regulations merely require, for traceback purposes, that certain poultry product containers be marked "by code or otherwise" with the date of packaging or the date on which the poultry was slaughtered, as appropriate. 9 C.F.R. Part 381.126. The regulations permit a calendar date to be declared on poultry product labels in accordance with the requirements specified in 9 C.F.R. Part 381.129(c).

Towns Q.4 -- In the wake of the E. coli O157:H7 outbreak Agriculture Secretary Espy testified before a Senate panel in February 1993 on the need for additional legislative authority. In November 1993, former Assistant Secretary Eugene Branstool testified before this subcommittee that USDA was preparing a legislative package to increase its ability to trace-back the source of pathogens and control their presence on meat and poultry products. What is the status of this legislative package and why has it taken so long to develop and submit to Congress?

The USDA pathogen reduction package is now undergoing review within the Administration. The proposal is broad and involves changes that affect several USDA agencies, and could have implications for agencies outside USDA. Also, the legislative proposal involves changes to several statutes, and the long-term effects of those changes needed careful and thorough consideration.

We regret that it has taken longer than we hoped to submit the proposal to Congress. However, we want to be sure the legislative package meets the needs, requirements and policies of the entire Administration.

Towns Q.5 -- According to a March 25, 1994, Reply Brief of Amicus Curiae United States, that USDA had previously submitted to the subcommittees, USDA has advanced its interpretation of the Poultry Products Inspection Act's (PPIA) preemption clause as an amicus curiae in Instituto Puertoriqueno de Carnes, Inc. v. Davila, Civil No. 92-2098 (HL) (D.P.R. 1992). The Reply Brief also indicates that this case was settled before resolution. What is USDA's understanding of this settlement? Please provide a copy of the amicus curiae brief and copies of all correspondence between USDA and Puerto Rico from March 1988 through the present concerning the PPIA's preemption clause.

On August 10, 1992, the Instituto Puertoriqueno de Carnes, a trade association of meat dealers and importers, sued the Department of Agriculture of Puerto Rico, challenging Puerto Rico's Market Regulation No. 8 (M.R. 8) on several grounds, including the claim that M.R. 8 imposed requirements on the shipment to and marketing within Puerto Rico of poultry products from the U.S. mainland that are preempted by federal law. The U.S. Department of Agriculture agreed with the plaintiff that certain provisions of M.R. 8 were preempted, and, on October 14, 1992, the U.S. Department of Justice, in consultation with USDA, filed an amicus curiae brief in federal court in Puerto Rico. The brief outlined the preemption provision contained in the Poultry Products Inspection Act, and delineated those "marking, labeling, packaging and ingredient" requirements of M.R. 8 which the U.S. government viewed as preempted. DOJ and USDA attorneys also appeared in court to argue the preemption issue at the hearing held the week of November 23, 1992.

The parties to the lawsuit settled their dispute during that week, and their settlement agreement was entered by the court as a consent decree on November 25, 1992. The consent decree identified and/or suspended certain portions of M.R. 8, including those provisions which imposed grading or labeling requirements additional or different from federal law. The November 25 consent decree also provided that the Secretary of Agriculture of Puerto Rico should commence, in consultation with the USDA, a process of revising and modifying M.R. 8 so as to develop new and/or modified regulations which will pursue the public policy of the Commonwealth of Puerto Rico without conflicting with federal law or regulations. The consent decree did not, however, remove or modify all provisions attacked by plaintiff or the U.S. Government. The Department, as amicus, was not a party to the Consent, and, in fact, informed the court that several provisions of M.R. 8, which were not to be modified by the settlement agreement, continued to raise preemption issues.

In December 1992, the Secretary of Agriculture of Puerto Rico filed modified regulations. The USDA was not provided the opportunity to review and comment on the modified regulations prior to their submission to the court.

It is our understanding that soon thereafter, the Instituto filed a motion with the district court challenging a labeling requirement in the revised M.R. 8. After hearing arguments from the parties, the court ruled that the provision did not violate the consent decree. Neither the USDA nor the Department of Justice was a party to this motion and did not participate. (An attorney with DOJ from the local U.S. Attorney's Office did attend a conference on this issue, but did not represent the government's position to the court.).

As Puerto Rico was advised in a subsequent letter dated July 1, 1993, representatives of the U.S. Department of Justice and USDA never ratified the terms of the consent decree and, in fact, advised the court that some provisions which the government viewed as being preempted by federal law were not addressed by the consent decree. Further, we did not authorize the provisions of the modified regulations containing the controversial labeling requirement. Accordingly, in a letter dated February 1, 1993, Secretary Espy advised Pedro J. Rossello, the Governor of Puerto Rico, that the requirement in M.R. 8 that the name and address of the importer appear on consumer size packages of all poultry products shipped into Puerto Rico was preempted by the Poultry Products Inspection Act.

The Secretary of Agriculture of Puerto Rico, Neftali Soto-Santiago, responded in a letter dated April 8, 1993, to Secretary Espy that Puerto Rico is giving "thorough consideration" to the preemption section in the PPIA, and that "[a]ny new regulation will comply with the requirements of the PPIA." As you requested, copies of these letters are attached.

Thereafter, in a letter dated April 14, 1993, Puerto Rico's Office of the Attorney General requested assistance from the USDA in revising M.R. 8 to comply with federal law. (See attached)

In response to Puerto Rico's request, and in order to expedite the resolution of the controversy surrounding M.R. 8, the USDA formed a committee of officials of the Department's Food Safety and Inspection Service and the Office of the General Counsel to review the December amendments to M.R. 8, and to provide consultation with representatives of Puerto Rico's Agriculture Department. Secretary Espy so informed Secretary Soto-Santiago in the July 1, 1993 letter referenced above, which stated that the USDA was "prepared to afford [Puerto Rico] whatever other assistance may be deemed necessary so that further legal confrontation can be avoided."

This action was followed with a letter dated July 6, 1993, from Dr. H. Russell Cross, FSIS Administrator, to Kermid R. Troche, Assistant Secretary of Agriculture, Puerto Rico, which outlined the preemption provision of the PPIA, and specifically delineated those provisions in M.R. 8 (December 92 amendments) which the USDA still considered to be preempted by federal law. Dr. Cross' letter requested that Puerto Rico consider the preemptive effects of the PPIA, and offered his assistance in these efforts, including offering to personally meet with Assistant Secretary Troche or his representatives. USDA followed up this letter with additional letters, which are attached. The Commonwealth has not sought to meet or consult further with USDA on these rules.

Subcommittee note: Referenced documents are retained in Subcommittee Files.

Towns Q.6 -- According to the written statement of Mr. Richard Rominger, Deputy Secretary of Agriculture, the Food Safety Inspection Service (FSIS) has reexamined its use of the USDA official inspection legend, "Inspected for Wholesomeness," which appears on Federally inspected poultry products. According to Mr. Rominger, the legend or seal "does not represent that the poultry product is sterile and completely free of pathogens." His statement also says that USDA will design its regulatory programs "through careful and deliberate consideration of the needs and expectations of the consumer, as well as the views of other interested parties, and consistent with sound scientific principles."

-- What specifically did FSIS do to "reexamine" its use of the official inspection legend? Did USDA conduct any consumer surveys or collect other data to determine consumer understanding and expectations about the legend? If yes, please provide a copy of these data, analyses and reports.

-- What data does USDA have on consumers' understanding and expectations of the "Wholesomeness" seal? What data does USDA have to establish that consumer know and understand that its official inspection legend "does not represent that the poultry product is sterile and completely free of pathogens?" Please provide copies of all such data.

At the Subcommittee's November 19, 1993 hearing, former Assistant Secretary Branstool promised to reexamine the official inspection legend given the fact that raw chicken cannot be guaranteed to be pathogen free.

The legend "inspected for wholesomeness" derives from a provision in the Poultry Products Inspection Act, which requires the Secretary to prescribe "a symbol . . . showing that an article was inspected for wholesomeness in accordance with the this Act." 21 U.S.C. § 453(m)(emphasis added). In 9 C.F.R. Part 381, the Secretary provided that the term "inspected for wholesomeness" means that "the poultry so identified has been inspected and was found at the time of such inspection to be not adulterated."

The legend indicates that poultry products, if properly stored, handled, and cooked, can be safely consumed. It does not mean that such products are pathogen free. Nor does it guarantee the wholesomeness of improperly handled or prepared products.

By their nature, raw meat and poultry products are not sterile or pathogen free, and the presence of pathogens in the raw products does not automatically render them adulterated. Consumers do not expect such raw products to be completely free of pathogens. A joint FDA-USDA health and diet survey performed in 1988 shows that 84% of consumers surveyed knew that raw meat and poultry juices are likely to contain germs, and that 85% knew that food that looks and smells acceptable may still be spoiled (survey attached).

We are also providing the Subcommittees with a Research Triangle Institute study performed under an FSIS contract dealing with, among other things, consumer impressions regarding

the meaning of the inspection legend. The Committee may also wish to review the attached 1992 survey regarding consumer attitudes toward food labeling that was received by the Department as comments on the Department's nutrition labeling rulemaking.

At Secretary Espy's direction, USDA has mandated, since July 6, 1994, new safe food handling regulations for all meat and poultry products that require preparation by cooking and are therefore not ready-to-eat. (Ready-to-eat products must, of course, be pathogen free.). The official legend on every poultry product must therefore be viewed in the light of the safe food handling information, which is also on the product. Since July 6, consumers purchasing poultry can read on the safe food handling label specific instructions for handling, cooking, and storing that, if followed, will ensure that they will be able to enjoy a wholesome and pathogen free poultry product. That set of instructions provides a context for the inspection legend, so that consumers can understand that the product will be wholesome if those conditions are met.

Subcommittee NOTE: Referenced documents are retained in Subcommittee files.

Towns Q.7 — What is the legal status of FSIS Policy Memoranda? What requirements exist regarding the development and implementation of policy memoranda, including contacts with members of the regulated industry and development of a supporting administrative record? Please provide a complete regulatory inventory of all operational FSIS Policy Memoranda.

The Food Labeling Division (formerly the Standards and Labeling Division) began issuing Policy Memoranda in 1980. Policy memos, such as the FSIS policy memos on "fresh," are written expressions of agency interpretations of agency statutes and regulations. They are issued to FSIS employees in order to interpret existing law and regulations, and provide internal guidance.

FSIS does not enforce as regulations anything other than regulations duly promulgated in accordance with the rulemaking provisions of the Administrative Procedure Act (APA). As made clear in FSIS Directives 2610.1 and 2610.2, FSIS Policy Memoranda and directives explain and provide guidance on existing law; they are not regulations and do not establish new law. FSIS issues these policy memos to ensure that existing law and regulations are interpreted and applied uniformly by FSIS employees. Although these FSIS issuances are directed primarily at FSIS employees, they are widely distributed and are accessible to the public and the regulated industry. They are on display in the FSIS FOIA Reading Room and are available to the public through the Government Printing Office.

Standards and Labeling Policy Memoranda result from the label approval process. The Memoranda are cleared at the branch level for signature by the Division Director. The PPIA's statutory scheme expressly permits the implementation of labeling policy on a case-by-case basis by requiring that all labels be individually approved by the Agency prior to shipment in interstate commerce and that challenges to USDA labeling decisions be made through individual adjudications. (21 U.S.C. Part 457 (c) & (d)). Instead of promulgating detailed regulations to deal with every eventuality in the every-changing arena of food labeling, USDA utilizes an elaborate pre-approval process. (21 U.S.C. 457 (c) & (d); 9 C.F.R. Part 381.132 (a)). Under this labeling approval scheme, no product is permitted to leave a poultry plant unless its label has been approved by FSIS officials as having complied with all USDA requirements. 9 C.F.R. Part 381.132(a). The label approval process includes a determination of compliance with existing policy memos of the staff, including the policy for use of the term "fresh." The USDA enforces these policy memos by disapproving non-compliant labels. USDA label approval practice reflects its interpretation of Federal requirements rather than establishing new requirements. A copy of the existing procedures is included.

Often, Policy Memoranda are the result of all the discussions and appeals that take place during the prior label approval process regarding a labeling or standards issue.

In many situations, Policy Memoranda are a preliminary step to future rulemaking. For example, in the absence of nutrition labeling regulations, Policy Memoranda were issued to identify the policies of the Agency until rulemaking could be effected. Labeling of similar products and similar situations then assume the uniformity that is needed to provide a level playing field for the industry and useful information to the consumer.

Subcommittee Note: Referenced documents are retained in Subcommittee files.

Towns Q.8 – What is the status of the USDA/FSIS Technical Advisory Group (TAG) on risk assessment? Has the group been dissolved or has its work been impaired in any way and, if yes, why?

In May 1994, the Risk Assessment Technical Advisory Group (TAG) was formed. This TAG is headed by Dr. Joseph Rodricks, a Principal with ENVIRON Corporation and former member of the National Academy of Sciences Risk Assessment Committee. The TAG includes a distinguished interdisciplinary team of risk experts comprised of: Dr. Adam Finkel, Center for Risk Management Resources for the Future; Dr. John Bailar III, Department of Epidemiology & Biostatistics, McGill University; Dr. Richard Williams, Center for Food Safety and Applied Nutrition, Food and Drug Administration; and Dr. Morris Potter, Division of Bacterial Diseases, Centers for Disease Control. This group is developing a methodology to assess health risks that will be implemented by each of the five farm-to-table TAGs: Animal Production; Slaughter; Processing; Risk Assessment; and Distribution, Handling and Preparation. Currently the Risk Assessment TAG is charged with revising a draft methodology paper which incorporates the comments from representatives of the other TAGs.

Once a risk assessment methodology is finalized, the Risk Assessment TAG will work with each of the five other TAGs to model the health risks for meat and poultry and identify the most likely sources of those risks during each stage in the process. These separate risk assessments will then be synthesized to provide an overall ranking of the identified risks and their likely sources.

Although the Risk Assessment TAG has not been dissolved, financial constraints have restricted their progress in part due to cutbacks for the five other TAGs who will be directly involved in this series of assessments. Insufficient funds have resulted in some TAG's offering limited assistance in developing the methodology and may potentially be unavailable for implementing the methodology once it is finalized. As for the Risk Assessment TAG, work has proceeded telephonically. A shortage of funds has limited the ability of members to meet collectively for in depth working sessions. Since ongoing and intense collaboration between the risk assessment TAG and other TAGs will be required, continued cost containment efforts are likely to substantially slow down if not stop any further work in this area.

Towns Q.9 -- Will the poultry enhancement program include microbial guidelines and testing requirements on raw poultry? Please explain.

The proposed poultry enhancement program lays the foundation for incorporating developing science, including rapid testing and microbial guidelines. The methodology for rapid in-plant testing is not available, nor is there sufficient data on which to base a guideline at this time. Any comments regarding data or rapid methodology would be appreciated during the comment period, and will be given serious consideration by the Agency.

Towns Q.10 -- Please provide a copy of USDA's proposed rule for mechanically separated red meat and advance notice of proposed rulemaking for mechanically deboned poultry products.

See attached copies.

Subcommittee NOTE: Referenced documents are retained in Subcommittee files.

Towns Q.11 -- To what extent do differences in USDA's regulations on carcass chilling procedures favor poultry over meat? What evidence exists to show "that poultry producers have pushed chilling technology in the direction of ensuring the maximum allowable water gain instead of in the direction of reducing water gain" as indicated in the draft memorandum from H. Russell Cross, former Administrator, FSIS, to Eugene Branstool, former Assistant Secretary, Marketing and Inspection Services that was provided to the subcommittee? What is the status of FSIS's reevaluation of policies and practices in both red meat and poultry carcass chilling? When will this activity be concluded?

Both meat and poultry carcasses need to be chilled after the animals have been slaughtered to prevent growth of pathogenic and other bacteria and degradation of the product. The poultry regulations require chilling of poultry carcasses to 40° F within two to eight hours depending on the size of the carcass. Currently, the meat regulations have no requirements for chilling carcasses. However, a regulatory proposal for meat has been drafted and is currently undergoing Departmental review and clearance.

Industry practices vary between poultry and meat. Immersion of poultry in ice and water has long been an industry practice in the United States. Water absorption is considered unavoidable by this chilling process, therefore a reasonable amount of water absorption is permitted by the poultry regulations (9 C.F.R. Part 381.66).

Immersion in water is not practical for meat carcasses because their weight is as much as 100 times that of poultry carcasses. Thus, chilling tanks are not a viable option for meat carcasses. Air chilling of carcasses in large coolers has always been the industry practice. Recently, the industry has developed a method of spraying carcasses during chilling to prevent loss of carcass weight due to dehydration. This is permitted by the Agency as long as there is no net increase in weight. FSIS Directive 6330.1, May 26, 1993, indicates that individual carcasses may show an increase in weight; the total cold weight of untrimmed carcasses from a shift's production may not be higher than the total hot weight of the same carcasses.

Looking at results from actual in-plant moisture tests in poultry plants, results from different plants utilizing the same equipment vary considerably. This indicates the possibility that some members of the poultry industry could lower the maximum moisture level which was based on technology available at that time.

FSIS's reevaluation of policies and practices regarding carcass chilling have been completed. Information has been developed regarding moisture absorption in poultry, and this information is being studied. FSIS is drafting a proposed rule setting temperatures and chilling requirements for meat carcasses and raw meat products.

Towns Q.12 -- What were the major findings of the Research Triangle Institute study on permitted exemption practices and what is the status of FSIS's review of this study?

In 1991, Congress directed USDA [1] to study the "appropriateness" of a blanket inspection exemption for wholesale meat and poultry processors that perform only cutting, grinding, slicing, and repackaging operations for sale to hotels, restaurants, and similar institutions (HRIs) and [2] develop and evaluate criteria for present and future meat and poultry product inspection exemptions.

Subsequently, the Food Safety and Inspection Service (FSIS) contracted with the Research Triangle Institute (RTI) to perform this work. RTI conducted this study and issued an extensive report which concluded as follows:

- Warehouse clubs and similar type establishments which process meat or poultry for commerce present the same risk to public health as presently-inspected wholesalers that perform the same processing operations.
- "Simple" processing such as cutting, grinding, slicing, and repackaging was judged by an independent group of experts not to be lower in risk than any other form of meat and poultry processes, as these processes are conducted in the current industry environment.
- The product exemption criterion that is based upon low percentage of meat or poultry has worked well up to the present time, and there is no evidence that foods exempted by this criterion have presented any public health problem or adversely affected the regulated industry. Further, it has been an important tool for focusing inspection resources on the manufacturing plants Congress intended to be covered by the FMIA & PPIA.
- Sufficient doubt exists about the scope and intent of the FMIA and PPIA "consumer perception" exemption criterion to warrant a reconsideration of all product exemptions granted by USDA under this provision since the mid 1960's.

FSIS concurred with the RTI findings and prepared a draft report which is currently under review in the Department.

Subcommittee Note: Referenced document is retained in Subcommittee files.

Condit Q.1 -- What are the USDA's, or FSIS's, guidelines on meeting with industry officials concerning matters that are pending regulation? Are employees required to keep any type of logs, files, memoranda, etc.?

We are attaching an Informal Guide to Rulemaking prepared by the Department's Office of the General Counsel that is distributed to agency officials. The Committee should note that the FSIS uses informal rulemaking procedures only. It does not engage in formal rulemaking procedures that require separation of functions to preclude "ex parte communications" that may bias the proceedings.

FSIS officials involved in informal rulemaking under the Administrative Procedure Act are routinely counseled by FSIS' Regulations Development staff and by Departmental Office of General Counsel attorneys as appropriate on relevant APA requirements, as interpreted by the courts. Generally, FSIS personnel involved in rulemaking activities are counseled as follows:

At the pre-proposal stage, the agency, consistent with Executive Order 12866, issued by President Clinton on September 30, 1993, encourages free and open communications with the regulated industry and others on matters that may be appropriate for rulemaking. Records of communications are kept at the discretion of the employee. Persons advocating changes to the regulations are requested to submit a written petition to the agency (see, FSIS Petition Submission and Review Procedures, 58 FR 63570 (Dec. 2, 1993)).

Once a proposed rule has been published, all commenters must be treated alike, and all comments must be made a part of the administrative record. Discussions about the proposal are limited, on the agency's part, to explaining the proposal as drafted. Explanation of the proposal helps ensure informed comments are received on a timely basis. Agency personnel are advised to not discuss the possible disposition of proposals with any interested parties.

The agency encourages the submission of written comments on its proposed rules. However, under the Poultry Products Inspection Act (21 U.S.C. § 463(c)), the agency also accepts oral comments on those proposals affecting the poultry regulations. Oral comments are made to the designated agency contact, who is responsible for providing a memorandum to the administrative record describing the comment. An information copy of the memorandum is sent to the commenter. The Federal Meat Inspection Act (FMIA) does not contain a similar provision.

After the close of the comment period, agency personnel involved in the rulemaking are not to discuss substantive areas of that rulemaking with any interested parties. Any further opportunity to comment must be afforded to all persons equally, thereby requiring extension or reopening of the comment period.

Condit Q.2 -- Do any of the guidelines from above apply to matters that are to be decided through the use of a "policy memo?" Are there any separate guidelines concerning industry contact during the formulation of a policy memo?

Different procedures apply. Labeling Policy Memoranda are not regulations. They are guidance provided to Inspection Program personnel who must review labels submitted to the agency for approval. They are issued on an as needed basis by the Director of the FSIS Labeling Division, and advise reviewers how a particular issue that arose in the context of a label review has been resolved and, if arising again, may be similarly resolved. This promotes more uniform and equitable decisionmaking on labeling applications. Policy Memos are widely distributed to the industry and others, generally through the Freedom of Information Act requests.

FSIS encourages free and open communication between the regulated industry and Inspection Program personnel on labeling policies. Anyone may request reconsideration of a policy memorandum (or, for that matter, any other FSIS guidance issued to FSIS personnel and/or the industry) at any time. As a practical matter, such requests are normally received from companies or segments of the industry who believe they will be adversely affected by application of the policy to their product. Such requests may be received at any level of the Department or agency, and are forwarded to the Labeling Division (or other appropriate office) for disposition. Labeling Division and other affected personnel use their discretion in maintaining working files as needed on specific labeling policy issues. Such files are accessible under the FOIA.

Condit Q.3 – Is it the FSIS's opinion that it does not in any way regulate the information printed upon boxes of poultry product that are delivered to the retailer. Specifically, the picture of the Tyson shipping box placed into the hearing record indicated that "the freezing point of poultry is 28-32 degrees." This information actually contradicts the spirit, if not the letter, of Policy Memo 022C. Is it the FSIS position that this information is correct or incorrect. If it is incorrect, is it beyond the scope of FSIS to order a change in the message?

Information printed on boxes of poultry products is subject to the authority of FSIS (9 C.F.R. Part 317.8). The Labeling staff is reviewing the statement in question since the issue was brought to our attention. It is generally recognized that poultry will not begin to freeze until some temperature below 32 degrees F is reached. The presence of various natural substances in poultry lower the freezing point of poultry to some point below that of water, i.e., 32 degrees. In those situations, where it is determined that a label is false or misleading, the Agency orders the withdrawal of the use of that label.

Condit Q.4 -- Was the issue of fresh vs. frozen in any way considered during the deliberations that led to the new nutrition labeling or safe handling and cooking labeling on raw products that will take effect on July 6, 1994. If so, specifically what criteria were used?

The issue of fresh vs. frozen poultry was not addressed in FSIS's rulemaking on nutrition labeling or safe handling statements.

Condit Q.5 -- Please supply the Subcommittee with a list of the scientific literature produced since January 1, 1990 that has been reviewed as part of the "reevaluation" of fresh labels on poultry.

A list is attached of all references available in the Agency's review of the "fresh" issue.

PRELIMINARY SUMMARY

PART I

CHANGES IN THE PHYSICAL (ORGANOLEPTIC) CHARACTERISTICS OF
POULTRY AS THE TEMPERATURE CHANGES

Perishable foods such as poultry are subjected to certain physical and chemical changes during the freezing process which may affect their eating quality. The formation of ice crystals may rupture the cell walls causing textural changes which may affect consumers' acceptance. If the poultry is frozen rapidly and thawed, the quality degradation of the product is minimized. The Agricultural Research Service's preliminary literature search indicates there is no recent research assessing the sensory differences between poultry that has been frozen and that which has not been frozen.

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PRELIMINARY SUMMARY

PART II

EFFECTS OF TEMPERATURE ON SPOILAGE MICROORGANISMS

Current scientific information indicates that perishable poultry products can be safely stored at temperatures up to 40° F for a finite period of time. However, some microbial growth may still occur which eventually leads to spoilage. Cold-tolerant bacteria causing spoilage have been shown to multiply at temperatures as low as 10° F.

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PRELIMINARY SUMMARY

PART III

EFFECTS OF TEMPERATURE ON PATHOGENIC MICROORGANISMS

The growth and multiplication of pathogenic or hazardous bacteria associated with poultry can be minimized by storing the product at temperatures in the range of 0° F to 28° F. The lower the temperature the lower the potential hazard. Historically, pathogenic bacteria were believed not to multiply at temperatures lower than 45° F. However, more recent information indicates that certain cold-tolerant bacteria, such as *listeria monocytogenes*, are pathogenic and are capable of multiplication at temperatures less than 32° F. To date, cold-tolerant bacteria causing spoilage have been shown to multiply at temperatures as low as 10° F. The safest product temperature would be the temperature at which all water in the product becomes frozen and microbial growth stops. The currently available scientific information indicates this temperature to be about 0° F.

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Modern Food Microbiology 1978

Second Edition

JAME H. JAY

D. van Nostrand Company New York

Schiff Q.1 -- Please provide a copy of all written ethical guidelines for employees at the U.S. Department of Agriculture to each Member of the two subcommittees.

See attached material.

Subcommittee note: Referenced documents are retained in Subcommittee files.

Thurman Q.1 -- Please provide the toll-free number for USDA's meat and poultry hotline and information on the hot-line to disseminate to constituents, especially information on consumer guidelines for refreezing poultry products.

On June 22, 1994, the attached USDA Meat and Poultry Hotline information packet was sent by Patricia Jensen, Acting Assistant Secretary for Marketing and Inspection Services, to all members of the Subcommittee on Human Resources and Intergovernmental Relations and the Subcommittee on Information, Justice, Transportation and Agriculture. A copy of Ms. Jensen's letter, which accompanied the information packet, is also enclosed.

Consumer guidelines for refreezing poultry products are also attached.

Honorable Edolphus Towns
Chairman, Subcommittee on
Human Resources and
Intergovernmental Relations
2232 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

The enclosed food safety information packet is being supplied to you per a request made by one of your colleagues at the June 16, 1994, Government Operations Committee's joint subcommittee hearing on the labeling of poultry as fresh. We wanted to make sure you were aware of the USDA Meat and Poultry Hotline and the services it provides.

USDA's Meat and Poultry Hotline provides food safety information to consumers, health professionals, government officials, community leaders, and Members of Congress. Should your constituents have food safety questions, they may contact USDA's Meat and Poultry Hotline at 1 (800) 535-4555. The Meat and Poultry Hotline office is staffed with home economists and nutritionists and is open from 10:00 a.m. - 4:00 p.m. Monday thru Friday. At night and on weekends, hotline information is available through a 24-hour informational recording. Callers may select from the following eight categories: seasonal topics; food storage; food preparation and handling; power failures and other emergencies; foodborne illness; labeling and nutrition; recalls of meat and poultry products; and cooking equipment.

I hope this information is helpful. If you have any questions or need additional food safety packets, please contact Patrick Collins, Director of Information and Legislative Affairs, at 720-7943..

Sincerely,

Patricia Jensen
Acting Assistant Secretary
Marketing and Inspection Services



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Room 2925
Washington, DC
20250

**FOOD SAFETY INFORMATION PACKAGE
SUMMER 1994**

Dear Colleague:

Now that the ravages of the worst winter in years are mercifully over, it's not too soon to look ahead to the lazy, hazy days of summer -- especially when planning your food pages. So we're sending you this information package to help you get started.

Included are three features which can be used "as is": "Backpackers Get Food Safety Advice from USDA's Meat and Poultry Hotline," "Don't Forget to Pack Safety In Your Picnic Basket," and "'Grill' the USDA Hotline Experts About Safe Summer Cooking."

Also enclosed are four backgrounders: "Focus on Hot Dogs," "Focus on Summer Food Handling," "Focus on Safe Food to Go" and "Focus on Community Picnics," to help you personalize stories.

Finally, we have included a sheet of reproducible print ads which tell readers how they can "grill" the Hotline staff with summer food safety questions. This ad can be run at anytime.

Although we would appreciate some kind of attribution, all of the enclosed materials are in the public domain. If you have any questions, please call me direct at (202) 720-5604.

Your readers, of course, should call our nationwide toll-free Hotline when they have any questions concerning safe handling and preparation of meat and poultry products. The phone number is -- 1-800-535-4555. In Washington, D.C. -- (202) 720-3333.

Thank you for helping us in getting the word out about food safety.

Sincerely,

Susan Conley, Director
Meat and Poultry Hotline

Enclosures



FOOD SAFETY FEATURES

From USDA's Meat and Poultry Hotline

Susan Conley (202) 720-5604
Jerry Redding (202) 720-3310

"GRILL" THE USDA HOTLINE EXPERTS ABOUT SAFE SUMMER COOKING

WASHINGTON, D.C. — The lazy, hazy days between Memorial Day and Labor Day mark the time to break out the backyard barbecue grill.

This is also a good time to "grill" the experts from USDA's Meat and Poultry Hotline about cooking and handling foods safely to avoid food poisoning.

"Safe food handling is always important," says Susan Conley, director of the nationwide toll-free hotline, "but during the warm summer months — peak grilling season — there is an increased need for awareness of safe food handling practices."

Cases of foodborne illness do rise during the summer. The Hotline offers advice to consumers with questions about safe handling and preparation of meat and poultry products.

Here are some of the most common topics when callers "grill" the Hotline experts:

- **Marinating.** The Hotline advises to marinate raw meat, fish and poultry in a glass dish in the refrigerator — not on the counter. *"If you plan to use some of the marinade as a dip or basting sauce later, set aside a portion before adding raw meat or poultry to it,"* advises Marilyn Johnston, one of the experts on the Hotline. *"Don't re-use the marinade from raw meat unless you boil it for several minutes to destroy any bacteria from the raw meat."*
- **Pre-cooking.** Many Hotline callers ask about whether it's safe to save time on the grill by partially cooking meat or poultry ahead of time to finish up on the grill. *"Yes, it is safe, but only if the food goes immediately from the microwave or range to the grill,"* says Bessie Berry, senior home economist on the Hotline. *"Think of it as all one cooking process, and cook the meat thoroughly all at once."* Interrupted cooking is risky business. If you must cook ahead, cook the meat completely and then cool it fast for reheating on the grill later.

- **Cooking Thoroughly!** For safety and quality, the coals should be very hot before cooking food. It can take 30 minutes or longer before the coals are ready. They should show a light coating of ash for optimal heat.

"Meat and poultry should be thoroughly cooked," states Conley, "and it's best to use a meat thermometer to check for safety and doneness." Large cuts of beef like roasts may be cooked to an internal temperature of 145° F for medium rare and 160° F for medium. Whole poultry should reach 180° F.

"Don't eat raw or undercooked hamburgers made from meat or ground poultry since harmful bacteria could be present." To be sure bacteria are destroyed, cook meat patties to 160° F; ground poultry to 165° F.

"It's always a good idea to take an 'exploratory' cut into any patties, poultry, meat or fish to check doneness," says Conley, "because on the grill, often the outside looks done, but the inside is not. Juices should be clear and meat should not be pink."

- **Grilling and Cancer Concerns.** *"Worries about overcooking or charring foods brings more concerned callers," says Diane Van, another hotline food safety specialist. "We get a lot of calls from people who are afraid to grill because they have heard consuming grilled foods could be linked to cancer. As long as you're not cooking every breakfast, lunch and dinner on the grill, there shouldn't be a problem. The answer: moderation."*

The American Cancer Society suggests trimming visible fat that could make the fire flame up and char the food. Pre-cooking in the microwave and conventional oven also lessen grilling time and reduce risks. The Society also suggests raising the cooking level of the grill so food is farther from the heat, avoid eating charred or burned portions of food and clean the grill thoroughly after cooking.

- **Serving Grilled Food.** Serve hot, grilled foods immediately. Put cooked foods on clean plates that weren't used to hold the raw meat or poultry. Perishable foods should be consumed within two hours, one hour if the outside temperature is above 90° F.
- **Cleaning Up.** Clean the grill after each use. *"Also, refrigerate any leftovers promptly," advises Conley. "Divide larger quantities into small, shallow containers."*
- **Taking Leftovers Home.** A number of Hotline callers ask about the safety of taking home perishable foods from picnics. Barbara O'Brien, a registered dietitian on *"the line"* suggests, *"If you are returning home from an outing within four to five hours, and your perishables were on ice except when cooked and served, you should be able to save the leftovers. Be sure the foods are refrigerator cold to the touch and ice or a cold source remains when you arrive home."*

For more information about grilling or other questions about safe handling of foods, call the Meat and Poultry Hotline at 1-800-535-4555. In the Washington, D.C. area, call (202) 720-3333.



Food Safety Features

From USDA's Meat and Poultry Hotline

Susan Conley (202) 720-5604

Jerry Redding (202) 720-3310

DON'T FORGET TO PACK SAFETY IN YOUR PICNIC BASKET

WASHINGTON, D.C.—As the saying goes, *"There are always ants at a picnic."* While you can see ants and avoid them, it's not possible to see, taste or smell dangerous bacteria that can cause illness if food is mishandled.

So, before leaving home for a picnic, be sure you have packed safety in your basket. This means preparing and storing food safely first; then packing it for traveling safely.

Hotline director Susan Conley says, *"With great weather, holidays and the end of school coming, picnics will be in season. However, it's also the season when more people become ill from foodborne bacteria."*

Why? Bacteria grow and multiply rapidly in the danger zone between 40° F and 140° F (out of the refrigerator or before food begins to cook.) So, food transported without an ice source or left out in the sun at a picnic won't stay safe for long.

Family and friends who eat mishandled food may get what's known as *"Summer Tummy,"* or *"Summer Bug,"* pseudonyms for the flu-like symptoms caused by foodborne illness.

The USDA Meat and Poultry Hotline offers the following tips for packing a safe picnic basket:

- Try to plan just the right amount of foods to take. That way, you won't have to worry about the storage or safety of leftovers.
- Clean preparation is essential. Wash hands and work areas; be sure all utensils are clean before preparing food.
- Cook foods in plenty of time to thoroughly chill them in the refrigerator. Then use an insulated cooler with sufficient ice or ice packs to keep the food at 40°F. Pack food right from the refrigerator into it.

- If you're planning on take-out foods such as fried chicken or barbecued beef, eat them within two hours of pick up or buy ahead of time and chill before packing the foods into the cooler.
- Don't put the cooler in the trunk; carry it inside the air-conditioned car.
- At the picnic, keep the cooler in the shade. Keep the lid closed and avoid repeated openings. Replenish the ice if it melts.
- Except when it's being served, the food should be stored in a cooler. Use a separate cooler for drinks so the one containing perishable food won't be constantly opened and closed.
- When handling raw meat, remove from the cooler only the amount that will fit on the grill. The USDA recommends against eating raw or undercooked ground beef since harmful bacteria could be present.
- To be sure bacteria are destroyed, cook hamburgers and ribs to 160° F (medium doneness) or until the center is no longer pink and the juices are clear. Cook ground poultry to 165° F and poultry parts to 180° F. Reheat pre-cooked meats until steaming hot.
- Do not partially grill extra hamburgers to use later. Once you begin cooking hamburgers by any method, cook them until completely done to assure that bacteria are destroyed.
- When taking foods off the grill, don't put the cooked items on the same platter which held the raw meat.
- Leftovers? Place foods in the cooler promptly after grilling or serving. Any left outside for more than an hour should be discarded. If there is still ice in the cooler when you get home, the leftovers are okay to eat.

Remember, bacteria can be present in most any food as well as on people's hands. Safe food handling is essential for safe picnics.

For further information about the safe cooking and handling of foods for picnics, call USDA's Meat and Poultry Hotline at 1-800-535-4555. Washington, D.C. area residents call (202) 720-3333.



FOOD SAFETY FEATURES

From USDA's Meat and Poultry Hotline

Susan Conley (202) 720-5604

Jerry Redding (202) 720-3310

BACKPACKERS GET FOOD SAFETY ADVICE FROM USDA'S HOTLINE

WASHINGTON, D.C. — Getting away and exploring the great outdoors is a favorite American pastime. But for some people "getting away from it all" doesn't mean just visiting one of our national parks, but putting on a backpack and hiking far off into the wilderness. The scenery is beautiful, the air is clean, the peace and quiet is refreshing — but WHAT DO YOU EAT?

The Hotline advises backpackers who will carry their meals on their backs to plan their menus with food safety in mind as well as such other considerations as the weight of the food, preparation, and trash disposal.

"Food poisoning bacteria grow rapidly at warm temperatures," according to Susan Conley, Director of the U.S. Department of Agriculture's Meat and Poultry Hotline. *"Many of our favorite foods are perishable and require refrigeration. Even a day hiking in the wilderness with perishable foods stored improperly could result in foodborne illness."*

Raw meat, poultry, fish, most dairy products, eggs (even hard-cooked eggs) and prepared foods should be stored cold, that is, at 40° F or colder and should not be left unrefrigerated for more than two hours.

Keep portion sizes in mind as you plan your menu: leftovers are not desirable! Check first to see if campfires are allowed, or if you will have to bring a stove. When cooking foods, be sure to cook them thoroughly. Cook meat, poultry and fish thoroughly to ensure that food poisoning bacteria have been destroyed.

When planning a menu for a hiking trip, many backpackers choose foods that do not require refrigeration. Canned meat, poultry, and fish — although heavy — are good choices (just remember the can opener!).

In addition to canned foods, there are many foods that do not require refrigeration: peanut butter and jelly; hard cheeses; dried meats, fruits, and nuts; dried noodles and soups; breads and crackers; powdered milk and fruit drinks. Concentrated juice boxes are also handy, although heavy. Check with an outdoor supply store for foods packaged especially for backpacking.

Of course, if you pack carefully it is possible to use fresh foods for meals the first day. Many campers drive to their campsites with coolers, and have access to grills.

Foods can be prepared in advance, refrigerated or frozen, and packed with a cold source. Freeze water in a plastic jug and wrap it with the frozen foods in a plastic bag, then stuff the bag inside a sleeping bag (or something else) in your backpack. This way the food will be kept cold while you hike.

"Water is always an important consideration on a hiking trip," says Conley. "You'll need it for preparing foods as well as for washing up. Always assume that stream and river waters are not safe to drink and may contain bacteria that could cause illness if the water is not purified before drinking."

Purchase purification tablets or equipment from camping supply stores, and learn purification techniques. Although heavy, you may wish to bring along some bottled water.

Cleanliness is essential. Pack soap for hand- and dishwashing. Or use disposable wipes to clean your hands when working with food. But remember: disposable doesn't mean leaving it behind to pollute the great outdoors. Burn disposable wipes, paper towels and leftover food.

A special note to hiking families: if you are backpacking with an infant, carry pre-measured packets of powdered infant formula as well as bottled water; and prepare one bottle at a time. If carrying prepared bottles they must be kept cold.

If using bottled water, it is not necessary to boil it before mixing with formula. As for baby food, bring the smallest size jars and dispose of any leftovers after eating (as well as leftover formula).

For more information, call the USDA's Meat and Poultry Hotline, 1-800-535-4555.
In the Washington, D.C., area call (202) 720-3333.



FOOD SAFETY Focus

From USDA's Meat and Poultry Hotline

FOCUS ON: SAFE FOOD TO GO

For bag lunches, picnics or celebrations away from home, food can be kept safe if it is first handled and cooked safely. Then, keeping food cold while transporting and serving as well as practicing safe grilling techniques can prevent foodborne illness.

Beginning with Safe Food

Perishable food must be kept cold or frozen at the store and at home. In between, the food should be at room temperature or in the car as little time as possible. Then it must be kept cold or cooked and chilled. Food should not be out of the refrigerator or oven longer than two hours.

If cooking foods beforehand--such as turkey, ham, chicken and vegetable or pasta salads, prepare them in plenty of time to thoroughly chill in the refrigerator. Divide large amounts of food into small containers for fast chilling and easier use. Keep cooked foods refrigerated until time to leave home.

Packing for Outings

If taking food away from home--on a picnic, for example--try to plan just the right amount of perishable foods to take. That way, you won't have to worry about the storage or safety of leftovers.

Items which don't require refrigeration include fruits, vegetables, hard cheese, canned meat or fish, chips, bread, crackers, peanut butter, jelly, mustard and pickles. You don't need to pack them in a cooler.

Some people like to keep raw hamburger patties frozen. At the picnic, be sure to grill them until the centers are no longer pink.

It's perfectly safe to store uncooked patties as well as raw steaks, ribs, chops, and raw poultry in the refrigerator for a day or so until ready to pack the cooler.

If marinating meat and poultry, store it in the refrigerator--not on the counter. If you plan to use some of the marinade as a sauce, reserve a portion before putting raw meat in it. Don't reuse the marinade from meat unless it's boiled first to destroy any bacteria that may have been on the raw meat.

Purchasing Take-Out Food

If you're planning on purchasing take-out foods such as fried chicken or barbecued beef, eat them within two hours of pick up. Otherwise, buy cooked foods ahead of time to chill before packing them into the cooler.

Keeping Cold Food Cold

After estimating the amount of food which needs to be kept cold, pack an insulated cooler with sufficient ice or gel packs to keep the food at 40° F. Pack food right from the refrigerator and/or freezer into it.

Why? Bacteria grow and multiply rapidly in the danger zone between 40° F and 140° F (out of the refrigerator or before food begins to cook.) So, food transported without an ice source or left out in the sun at a picnic won't stay safe long.

If packing a bag lunch or lunch box, it's fine to prepare the food the night before and store the packed lunch in the refrigerator.

To keep the lunch cool away from home, pack a small frozen gel pack or frozen juice box. Of course, if there's a refrigerator at work, store perishable items there upon arrival. Leftover perishables which have been kept refrigerated should be safe to take home. But once gel packs and other cold sources melt, perishables are not safe; discard them.

When taking food to a picnic, don't put the cooler in the trunk; carry it inside the air-conditioned car. At the picnic, keep the cooler in the shade. Keep the lid closed and avoid repeated openings. Replenish the ice if it melts.

Serving Food

Except when served, the food should be stored in a cooler. Just like a refrigerator at home when the power is off, the more times you open a cooler, the more cold air will escape. Once the ice melts, the cooler won't be able to keep food safe. Keep cold drinks in a separate cooler to avoid constantly opening the one containing perishable foods.

If you've packed cooked foods in several small containers, you can serve one and keep the others cold for second helpings. Leave raw meat in the cooler, too. When cooking it, remove from the cooler only the amount that will fit on the grill.

Grilling Safety

For safety and quality, the coals should be very hot before cooking food. For optimal heat, burn them 20 to 30 minutes or until they are lightly coated with ash.

The USDA recommends against eating raw or undercooked ground beef since harmful bacteria could be present. To be sure bacteria are destroyed, cook hamburgers to 160° F. Cut into the patty to be sure the center is no longer pink and the juices are clear. Large cuts of beef such as roasts may be cooked to 145° F, medium rare, or to 160° F for medium. Cook ground poultry to 165° F and poultry parts to 180° F. Reheat pre-cooked meats until steaming hot.

When taking foods off the grill, don't put the cooked items on the same platter which held the raw meat. Raw meat juices can contain bacteria that could cross contaminate safely cooked foods.

Do not partially grill extra hamburgers to use later. Once you begin cooking hamburgers by any method, cook them until completely done to assure that bacteria are destroyed.

Keeping Leftovers Safe

Place leftover foods in the cooler promptly after grilling or serving. Any left outside for more than an hour should be discarded.

For the return trip, the cooler should again travel in the air conditioned part of the car. If you were gone not more than four or five hours and your perishables were kept on ice except when cooked and served, you should be able to use the leftovers.

Check the cooler when you get home. If there is still ice in the cooler and the food is refrigerator-cool to the touch, the leftovers should be safe to eat.

Contact List

Susan Conley, Director, USDA Meat and Poultry Hotline,
202-720-5604. Consumers and the media may call USDA's Meat and Poultry Hotline tollfree at 1-800-535-4555. Washington, D.C. area residents call (202) 720-3333.

National Agricultural Library,
Food and Nutrition Information Center (301) 504-5719

Local Cooperative Extension Service

Related Publications Available from the Hotline

"A Consumer Guide to Safe Handling and Preparation of Ground Meat and Ground Poultry"

"Safe Food to Go"

"Escherichia coli Update: E. coli 0157:H7"
(FSIS Backgrounder)

"Food Safety on the Road"

"Food Safety and the Weekend Camper"

"A Boater's Guide to Food Safety"

"Food Safety at the Beach"

"The Egg Handling Handbook"

"Preventing Foodborne Listeriosis"



FOOD SAFETY Focus

From USDA's Meat and Poultry Hotline

FOCUS ON: COMMUNITY PICNICS

There is nothing more "all-American" than the community picnic: friends and neighbors, softball and sack races, and lots of good food. But someone has to cook all that good food, and if it's not handled safely, foodborne illness can become an uninvited guest. Here are some tips from USDA's Meat and Poultry Hotline to help you make sure your picnic treats are safe to eat.

Planning

Ideally, your picnic location should have facilities for washing hands and utensils. Handwashing is critical to prevent the spread of pathogenic bacteria. If no facilities are available, disposable towelettes are the next best thing. Plan to bring soap and water for washing hands and cookware.

Plan the menu with an eye to safe food handling. If the picnickers will be bringing the food, make sure that everyone's prize recipes are checked to be sure techniques used will be safe. Discourage people from preparing recipes that contain raw eggs, such as cream pies or home-made ice cream.

You may wish to send out a notice reminding your cooks to bring cold foods in coolers. Remember that perishable foods like meat, poultry, fish, eggs, and salads must be kept cold. Food poisoning bacteria grow rapidly at temperatures warmer than 40° F so these foods must be stored in coolers or on ice.

Preparation

Improper cooling is one of the most common causes of foodborne illness. If your group will be preparing large quantities of food, such as lasagna, barbecue, or roasts, in advance of the picnic, be sure it is cooled rapidly in small, shallow containers. In the case of roasts or whole turkeys your cooks will need to slice the meat up into chunks and refrigerate or freeze it in pans or platters. Trays of lasagna are fine but barbecue, chili, or stews should be cooled in shallow pans. Picnic foods can be prepared a day or two before the event.

A common problem is finding room to store all the food that has been cooked in advance. If your organization has a large refrigerator, you may wish to lower the temperature a few degrees to help cool foods quickly. Otherwise recruit volunteers to refrigerate or freeze foods in their home refrigerators, but be sure to stress to them that the foods must be stored at 40° F or colder.

Partial cooking is never a good idea. Often people will try to save time by partially cooking chicken, ribs, or even whole turkeys in advance and then finishing them up on the grill. This method can permit pathogenic bacteria to multiply while making it impossible to kill them through cooking. To save time foods that will be grilled can be cooked **thoroughly**, then *reheated* on the grill.

Coolers

There are limits to how long hot or cold food can be transported safely. Food should be packed to take to the picnic in sturdy, insulated coolers with plenty of ice or frozen gel packs.

Remember the two-hour rule. Perishable foods must be kept hot or cold, and should not be allowed to sit at temperatures warmer than 40° F for more than two hours. In the summertime, don't let food sit out for more than one hour. If your food is being delivered, make sure the person bringing it has a way to keep it hot or cold.

Designate certain coolers for beverages and allow those containing foods for the picnic to remain undisturbed. Cover these coolers with blankets and place them in the shade to help hold the cold temperature.

Cooking Food at the Picnic

Whether cooking indoors or outside on a grill, meat and poultry must be cooked thoroughly to ensure that pathogenic bacteria are destroyed. Grill raw poultry until the juices run clear and there is no pink close to the bone. Likewise, burgers should not be pink in the center.

Cooked foods are just as perishable as raw, so once grilled foods are cooked do not let them sit out for more than an hour or so. Try to pace the preparation so that food is eaten shortly after it is cooked.

Take-out foods or foods cooked just before being transported to the picnic can be carried hot. Those who will be bringing hot food can wrap it in towels, then newspaper, and place it inside a box or brown bags. These foods should be kept warm on the grill.

Leftovers

Chances are, picnic leftovers have been sitting out for more than an hour or two. Discard these leftovers.

Cold foods that were kept in a cooler that still has ice may be safe. If the ice has melted, the food should be discarded. Discourage your picnickers from taking home leftover warm meat, poultry, other cooked foods or salads.

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Local Cooperative Extension Service

Related Publications Available from the Hotline

"Safe Food to Go"
"A Quick Consumer Guide to Safe Food Handling"
"Food Safety on the Road"



FOOD SAFETY Focus

From USDA's Meat and Poultry Hotline

FOCUS ON: HOT DOGS

Whether you call it a frankfurter, hot dog, wiener or bologna, it's a cooked sausage and a summertime favorite. They can be made from beef, pork, turkey or chicken — the label must tell which. And there are federal standards for their content.

Definition

Frankfurters, hot dogs, wieners or bologna are cooked smoked sausages. They are a comminuted (reduced to minute particles), semisolid product made from one or more kinds of raw skeletal muscle meat and may contain poultry meat. Smoking and curing ingredients contribute to flavor, color and preservation of the product. They come in all sizes and shapes — short, long, thin and chubby. The most popular of all categories, the skinless varieties, have been stripped of their casings after cooking. The finished products may not contain more than 30% fat. Water or ice, or both may be used to facilitate chopping or mixing or to dissolve curing ingredients. Sausages may contain no more than 10% water and 30% fat or a combination of 40% fat and added water. Up to 3.5% non-meat binders and extenders such as nonfat dry milk, cereal, dried whole milk or 2% isolated soy protein may be used but must be shown in the ingredient statement by its common name.

Byproducts, Variety Meats

Frankfurter, hot dog, wiener or bologna "With Byproducts" or "With Variety Meats" are made according to the specifications for cooked smoked sausages (above) except they consist of not less than 15% of one or more kinds of raw skeletal muscle meat with raw meat byproducts. The byproducts (heart, kidney or liver for example,) shall be accompanied by the name of the species from which derived and must be individually named in the ingredient statement.

Species

Beef Franks or Pork Franks are cooked, smoked sausage products made according to the specifications above but with meat from a single species and do not include byproducts.

Turkey Franks or Chicken Franks can contain turkey or chicken skin and fat in natural proportions of that found on a turkey or chicken carcass.

Ingredient Statement

All ingredients in the product must be listed in the ingredient statement in order of predominance from the one weighing the most listed first to the one weighing the least listed last.

Mechanically Separated Meat or Poultry

Carcass parts from which most of the meat has been removed still has usable meat attached. These parts are pushed under high pressure through equipment with openings so fine that a small amount of powdered bone the size of a grain of sand may pass through along with the remaining muscle meat and other soft tissue. This is called "*mechanically separated*" meat and, if used in a product, the label must so state. Since it may contain some finely powdered bone, "the label shall state the calcium content as a percentage of the U.S. RDAs if it contributes 20 milligrams or more of calcium to a serving of the product."

Mechanically deboned poultry does not have the same requirements as mechanically separated meat and is simply listed in the ingredients statement as "*chicken*" or "*turkey*."

Dating

Dating is voluntary and not required by Federal regulations. If a date is used, it must also state what it means.

- **Packing date** - date of manufacturing, processing or final packaging.
- **Sell-by date** - last day a retail store may offer the food for sale. Good approximately 5 to 7 days past sell-by date **IF** handled properly.
- **Use-by date** - date after which peak quality of product begins to lessen, but product **may** still be used.
- **Expiration date** - marks end of product's useful life or the last day to be used.

Food Safety Guidelines

The same general food safety guidelines apply to hot dogs as to all perishable products — "***Keep them Hot, Keep them Cold, Keep them Clean.***" Although hot dogs are fully cooked, if you choose to reheat them, make sure they are steamy hot throughout.

When you leave the grocery store with those hot dogs, head straight home and refrigerate or freeze them immediately. If there is a date on the package, follow those guidelines for use. If there is no date, hot dogs can be safely stored in the unopened package for 2 weeks in the refrigerator; once opened, only 1 week. For

maximum quality, freeze hot dogs no longer than 1 to 2 months. And of course, never leave hot dogs at room temperature for more than 2 hours, or in the hot summer months when the temperature goes to 90° F or above, no more than 1 hour.

Contact

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area residents call (202) 720-3333.

Reference

Code of Federal Regulations, Volume 9, Section 319.180

**Related
Publications
Available from
the Hotline**

"The New Food Label and You"

"Meat and Poultry Labels Wrap It Up"



FOOD SAFETY Focus

From USDA's Meat and Poultry Hotline

FOCUS ON: SUMMER FOOD HANDLING

Food safety is always important. But in the summertime, when temperatures are hotter and foods can reach the danger zone faster, it's more important than ever to be sure foods are handled properly. At the store, when transporting foods and when handling food at home are crucial times for keeping food at safe temperatures and for avoiding cross contamination.

Selecting Foods

When shopping for raw and cooked foods in the summertime, notice how the food is displayed in the store. It's always important to be sure food is being stored at the proper temperature but especially in the summertime when the outside air is warmer. Display cases may have to be put on a colder setting to compensate. Never choose packages which are torn or leaking.

Avoiding Cross Contamination

To guard against cross contamination, put raw meat and poultry into a plastic bag so meat juices won't drip on other foods such as lettuce and fruit that will be eaten raw.

When ordering food from the deli department, be sure the clerk washed his hands between handling raw and cooked items. Don't buy cooked items which are touching raw items in the display case.

Transporting Food Home

Put refrigerated or frozen items in the shopping cart after all other selections have been made. Then, head for the checkout counter.

Ask the bagger to put raw foods in bags separate from cooked foods and produce. When loading the car, keep perishable items inside the air conditioned car — not in the trunk.

Drive immediately home from the grocery. Make the food store your last stop before driving home. If you live farther away than 30 minutes, bring a cooler from home and place perishables in it for the trip home.

Storage of Food at Home

Unload perishable foods from the car first. Put them immediately into the refrigerator or freezer. Assuming the store wrap on meat and poultry is clean and not torn, refrigerate or freeze the package as is. Since repeated handling can introduce bacteria from your hands to meat and poultry, it's best to leave a product in its original packaging.

Otherwise, re-wrap products in clean plastic or aluminum foil. For long-term freezer storage (longer than two to three months), overwrap store packaging as an added barrier and protection from freezer burn.

If you want to divide perishable foods into smaller containers, remember to wash your hands first. Work as fast as possible so food isn't setting out on the counter long. Wash hands after handling raw meat and poultry, too.

Preparation

Clean preparation is essential. Be sure all work surfaces and utensils are clean before preparing food. Remember, bacteria can be present on any surface or food as well as on people's hands.

To sanitize cutting boards, counters and sinks, first wash with hot, soapy water. Make a solution of two teaspoons of chlorine bleach to a quart of water and let the solution set on surfaces for a few minutes. Then rinse with clear water and pat dry.

When planning a picnic or cooking outdoors, be sure there are plenty of clean utensils and platters for handling the raw foods and the food after cooking. Pack soapy sponges and wet towelettes for cleaning surfaces and hands.

Keeping Food at a Safe Temperature

When working with food in a summertime kitchen, it's important to handle it quickly and get it into the oven or the refrigerator as soon as possible.

For example, as soon as you take a package of raw ground beef out of the refrigerator, form it into patties and stack them between squares of wax paper. Don't put more than four in each stack; the cold air needs to reach the center to chill them fast. Overwrap the stacks and refrigerate or freeze them immediately.

Marinate meat and poultry in a covered dish in the refrigerator unless you will be cooking them within the hour.

Check the temperature of the refrigerator and freezer. Like the store's display cases, they may need to be put on a lower setting in the summertime. Keep a thermometer in your cold storage unit. The refrigerator should be maintaining 40°F or lower and the freezer should be keeping foods at zero degrees.

Thorough Cooking

Once food is in the oven or on the grill, it should stay there until done to a safe temperature. Partial cooking of foods allows bacteria to survive and multiply to the point subsequent cooking can't destroy them.

Cook ground beef, veal, lamb and pork to 160° F; ground turkey and chicken, 165° F. Whole fresh beef roasts can be cooked to 145° F (rare) if desired. Otherwise, cook red meats to 160° F; whole poultry to 180° F; poultry breasts and roasts, 170° F. Check for visual signs of doneness: poultry juices should run clear and meat should be tender; ground meat should not be pink.

Leftovers

Warm summertime air may slow the cooling of cooked foods. Divide foods into small shallow containers to help foods cool quicker. Put food directly in the refrigerator or freezer. Never refrigerate one large pot of food or a whole turkey, however. The center of these foods may still be warm the next day, making them unsafe.

Contact List

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"Food Safety and the Weekend Camper"

"A Boater's Guide to Food Safety"

"Food Safety at the Beach"

Grill Our Experts With Your Food Safety Questions

Call the USDA Meat and Poultry Hotline for food safety facts
1-800-535-4555

Washington, DC 720-3333
 10:00 am-4:00 pm Eastern Time

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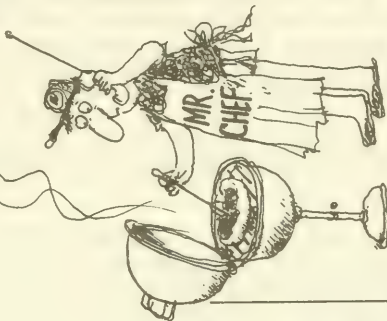
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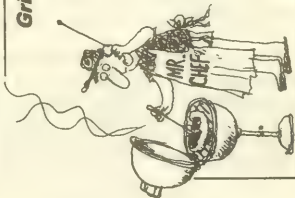
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Horn Q.1 -- According to the written statement of Henry J. Voss, Secretary, California Department of Food and Agriculture, several states other than California have enacted laws that deviate from Federal standards but USDA has not gone to court to challenge these other statutes. What other state laws deviate from USDA's meat and poultry statutes and regulations and what has USDA done or attempted to do about these deviations?

The USDA has advanced its interpretation of the explicit preemption clauses contained in both the Poultry Product Inspection Act and the Federal Meat Inspection Act in federal court on numerous occasions as a party and as an amicus curiae. For instance, in Grocery Manufacturers of America v. Gerace, 581 F.Supp. 658 (S.D.N.Y. 1984), and 755 F.2d 933 (2nd Cir.), cert. denied, 474 U.S. 820 (1985), as an additional defendant to Commissioner Gerace's counterclaim, the USDA asserted that New York's law was preempted under the PPIA. In 1992, in Instituto Puertoriqueno de Carnes, Inc. v. Davila, Civil No. 92-2098 (HL) (D.P.R. 1992), USDA argued that a Puerto Rico regulation was preempted by the PPIA, but the case, as you know, settled before resolution. USDA has also participated as amicus or otherwise in a number of cases involving federal preemption of state law under the Federal Meat Inspection Act. For example, in Jones v. Rath Packing, 530 F.2d 1295 (9th Cir. 1975), 530 F.2d 1317 (9th Cir. 1975), aff'd., 430 U.S. 519 (1976), the USDA filed an amicus brief in the United States Supreme Court urging affirmance of Ninth Circuit decision on preemption grounds. There are numerous other such cases in which the Department has participated.

Additionally, on various occasions, the Department has advised individual states that their poultry or meat labeling requirements, or other requirements or proposed requirements, appear to conflict with federal law, and has asked the states to take appropriate action. See for example, a 1987 letter from Secretary Lyng to California Governor Deukmejian and a 1994 letter to Joe F. Sanderson, Chairman, National Broiler Council, a copy of which was sent to the Oregon Attorney General's office, both of which are attached.

The Department does not systematically review all state and local laws independently of cases brought to its attention by the affected parties. Given the Department's limited resources, it would not be efficient for USDA to seek to learn of and challenge every preempted state requirement, some of which have little or no impact on commerce. Neither the federal meat or poultry statutes requires USDA to review independently the laws of each state and local government in order for the preemption provisions to be effective. In fact, with respect to the California "fresh" litigation, the Department chose not to become involved in the litigation until it was specifically requested by the court to participate as an amicus curiae.

In addition to the remarks of Mr. Voss, several documents filed in the California litigation make reference to state labeling or other laws which may deviate from federal requirements. As noted above, the Department simply does not have the resources to investigate the laws of every state and local governmental subdivision to determine whether they are preempted by federal law.

May 4 1994

Mr. Joe F. Sanderson, Jr.
Chairman
National Broiler Council
P.O. Box 988
Laurel, Mississippi 39441

Dear Mr. Sanderson:

This is in further response to your earlier letter about an Oregon labeling law (ORS 619.355) requiring that fryers sold in Oregon bear labeling that includes the State in which the poultry was produced.

As you know, the explicit preemption section in the Poultry Products Inspection Act (PPIA) (21 U.S.C. 467e) provides that marking, labeling, packaging, or ingredient requirements that are in addition to, or different from, those made under the PPIA may not be imposed by a State. The preemption applies to articles prepared at any official establishment under inspection in accordance with the requirements under PPIA. Further, a State may, consistent with requirements under PPIA, only exercise concurrent jurisdiction over articles required to be inspected that are adulterated or misbranded, as defined in PPIA, and also are outside such an establishment. This section also prohibits a State from imposing any requirement (other than certain consistent recordkeeping, access, and related requirements) within the scope of PPIA with respect to premises, facilities, and operations of any such establishment that are in addition to, or different from, those made under PPIA.

The Department of Agriculture (USDA) views these provisions as an integral part of the comprehensive regulatory scheme created by PPIA for poultry products. In establishing the system of inspection and other requirements to address the problems presented by poultry products that are unwholesome, adulterated, or misbranded, the Congress of the United States specifically found that the regulated articles are either in or substantially affect interstate or foreign commerce, and that regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions are appropriate to prevent and eliminate burdens upon and effectively regulate such commerce as well as to protect the health and welfare of consumers (21 U.S.C. 451).

Among other things, PPIA requires the condemnation of adulterated articles (21 U.S.C. 455(c)) and authorizes the Secretary to prescribe marking, labeling, and compositional requirements to prevent the distribution of articles with labeling that is false or misleading or that is otherwise misbranded (21 U.S.C. 453(h) and 457(b)). Articles found not to be adulterated must bear the inspection legend and other misbranding-related information when they leave an inspected establishment (21 U.S.C. 457 (a)). Although no article subject to PPIA may be sold or offered for sale by any individual or business unit in

Mr. Joe F. Sanderson, Jr.

2

commerce under any labeling that is false or misleading, the statute specifically permits labeling that is not false or misleading and is approved by the Secretary (21 U.S.C. 457 (c)). In that regard, USDA's Food Safety and Inspection Service does not require that a product's label or any other material accompanying such product (that is, other "labeling" under 21 U.S.C. 453 (s)) include the words "grown in _____," the blank to include the State in which the chicken was produced, as called for in ORS 619.355.

The State of Oregon should carefully consider the preemptive effects of Federal law before taking any further action to implement ORS 619.355. In addition to the explicit preemption language in the PPLA, I note that this issue has been addressed by the Federal courts in such cases as Jones v. Rath Packing Co., 430 U.S. 519, 97 S. Ct. 1305, 51 L. Ed. 2d 604 (1977); Animal Legal Defense Fund v. Provimi Veal Corp., 626 F. Supp. 278 (D. Mass. 1986), aff'd, 802 F. 2d 440 (1986); and Grocery Mfrs. of America, Inc. v. Gerace, 581 F. Supp. 658 (S.D.N.Y. 1984), 755 F. 2d 993 (2d Cir. 1985), 106 S. Ct. 69, 88 L. Ed. 2d 29 (1985).

We are sending a copy of your letter and this response to the Oregon Attorney General's Office for consideration. I hope this information responds to your concerns.

Sincerely,

Signea

MIKE ESPY
Secretary

cc: Terry A. Laggert
Attorney In Charge Financial Fraud Section
1162 Court Street, N.E.
Salem, Oregon 97310

OES

Asst. Sec. for M&IS

Al Eidvig, RP/CP Room 300 West End Ct.

Lester Nordyke, IO/FSR Room 4434

ECSAO

DRAFT:FSIS:ECSAO:CSW:tw:03/28/94:tw:04/05/94:2Sanderson:02-3045622

FINAL:FSIS:ECSAO:tw:04/22/94

File: Legislation
(OPT:RP/CP)

Information: PCertkin draft approved by OGC

[Signature] 4/26/94
ASSOCIATE ADMINISTRATOR
FOOD SAFETY AND INSPECTION SERVICE

DEPARTMENT OF AGRICULTURE
 CALIFORNIA
 WASHINGTON, D.C. 20250

June 12, 1987

Honorable George Deukmejian
 Governor of California
 Sacramento, CA 95814

Dear Governor Deukmejian:

As the Secretary of Agriculture, my duties include implementation of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.). These statutes, which are administered by the Department's Food Safety and Inspection Service (FSIS) (21 CFR 2.17(g)(2) and 2.55(a)(2)), require inspection at various businesses engaged in the slaughtering or other preparation or processing of various livestock and/or poultry products for human consumption and otherwise regulate the contents and composition and the marking, labeling, and packaging of the products they distribute. Approximately 780 slaughtering and/or further processing establishments in California currently operate under FSIS's meat and poultry inspection program. In addition, many of the other 7400 federally inspected establishments in the United States distribute meat, meat food products, and/or poultry products in California.

Several trade associations of businesses regulated under the FMIA or the PPJA recently contacted me to express concern regarding the possibility of action to enforce Section 25249.6 of Chapter 6.6 of the California Health and Safety Code, the "Safe Drinking Water and Toxic Enforcement Act of 1986." Section 25249.6 provides that no person in the course of doing business may "knowingly and intentionally expose any individual to a chemical known to the State to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10." Section 25249.11(f) further specifies that such warning "may be provided by general methods such as labels on consumer products, . . . posting of notices, . . . and the like, provided that the warning accomplished is clear and reasonable", and it requires that implementing regulations "to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller . . ."

I have concluded that these industry members' concern is legitimate. I recognize that Section 25249.10(a) provides that "Section 25249.6 shall not apply to...[a]n exposure for which federal law governs warning in a manner that preempts state authority." Nevertheless, the provisions of Chapter 6.6 and implementation-related developments to date raise serious questions about

whether the State of California is aware of the preemptive effects of Federal law in regulating meat, meat food products, and poultry products.

I call your attention, in particular, to the explicit preemption sections in both the FMIA and the PPIA (21 U.S.C. 467e and 678). These sections provide that marking, labeling, packaging, or ingredient requirements which are in addition to, or different than, those made under the FMIA or PPIA may not be imposed by a State with respect to articles prepared at any establishment under inspection in accordance with the requirements under title I of the FMIA or under the PPIA; a State only may, consistent with requirements under the FMIA or PPIA, exercise concurrent jurisdiction over articles required to be inspected thereunder for the purpose of preventing the distribution of such articles that are adulterated or misbranded, as defined therein, and also are outside of such an establishment. These sections also prohibit a State from imposing any requirement (other than certain consistent recordkeeping, access, and related requirements) within the scope of the FMIA or PPIA with respect to premises, facilities, and operations of any such establishment that are in addition to, or different than, those made under the FMIA or PPIA.

The Department views these provisions as an integral part of the comprehensive regulatory scheme created by the FMIA and PPIA for certain livestock and poultry products, respectively. In establishing the system of inspection and other requirements to address the problems presented by meat and meat food products and by poultry products which are unwholesome, adulterated, or misbranded, the Congress of the United States specifically found that the articles so regulated are either in or substantially affect interstate or foreign commerce, and regulation by the Secretary of Agriculture and cooperation by the States and other jurisdictions as contemplated therein are appropriate to prevent and eliminate burdens upon and effectively regulate such commerce as well as to protect the health and welfare of consumers (21 U.S.C. 451 and 602).

Among other things, the FMIA and PPIA require the condemnation of adulterated articles (21 U.S.C. 455(c), 604, and 606(b)) and authorize the Secretary to prescribe marking, labeling, and compositional requirements to prevent the distribution of articles with labeling that is false or misleading or that are otherwise misbranded (21 U.S.C. 453(h), 457(b) and (d), 601(n), and 607(c) and (e)). Articles found not to be adulterated must bear the inspection legend and other misbranding-related information when they leave an inspected establishment (21 U.S.C. 457(a) and 607(b)). While no article subject to the FMIA or PPIA may be sold or offered for sale by any individual or business unit in commerce under any labeling which is false or misleading, the statutes specifically permit labeling which is not false or misleading and is approved by the Secretary (21 U.S.C. 457(c) and 607(d)).

FSIS does not require that a product's label or any other material accompanying such product (i.e., other "labeling" under 21 U.S.C. 453(s) or 601(p)) include warnings of the type called for by Section 25249.6. In fact, it appears likely that the Department would regard labeling materials including such warnings about products properly bearing the inspection legend as misleading. FSIS will

Honorable George Deukmejian

3

not approve labeling material submitted for its review that is believed to be misleading, and it may direct that use of labeling be withheld unless modified as prescribed so that it will not be false or misleading (21 U.S.C. 457(d) and 607(e)). The FMIA and PPIA also prohibit various actions involving misbranding and transactions in misbranded articles (21 U.S.C. 458(a) and 610), and they provide detainer and seizure authority as to misbranded articles (21 U.S.C. 467a, 467b, 672, and 673).

I recommend that the State of California carefully consider the preemptive effects of Federal law before taking any further action to implement Section 25249 as regards meat and meat food products or poultry products. In addition to the Federal statutes involved, particularly the FMIA and the PPIA, I note that this issue has been addressed by the Federal courts in such cases as Jones v. Rath Packing Co., 430 U.S. 519, 97 S.Ct. 1305, 51 L.Ed.2d 604 (1977); Animal Legal Defense Fund v. Provimi Veal Corp., 626 F.Supp. 278 (D.Mass. 1986), aff'd, 802 F.2d 440 (1986); and Grocery Mfrs. of America, Inc. v. Gerace, 581 F.Supp. 658 (S.D.N.Y. 1984), 755 F.2d 993 (2d Cir. 1985), 106 S.Ct. 69, 88 L.Ed.2d 29 (1985).

Thank you for your consideration of this matter.

Sincerely,

/s/ Richard E. Lyng
Secretary

Horn Q.2 – Please provide curricula vitae for the three USDA witnesses that appeared before the Subcommittees: Mr. Richard Rominger, Deputy Secretary; Mr. Terry Medley, Acting Administrator, FSIS; and Mr. John Golden, Associate General Counsel for Regulatory and Marketing.

See attached material.

NEWS

United States
Department of
Agriculture

Office of
Public Affairs

News Division
Room 404-A
Washington, D.C. 20250

Biography

RICHARD E. ROMINGER Deputy Secretary of Agriculture

Richard E. Rominger was nominated for the post of deputy secretary of agriculture by President Clinton, and was sworn in on May 12, 1993.

As deputy secretary, Rominger assists Secretary Mike Espy in supervising the activities of the U.S. Department of Agriculture, one of the largest and most diverse departments in federal government. USDA's mission includes management of traditional farm programs, domestic food assistance, research and education, agricultural marketing, international trade, meat and poultry inspection, forestry and rural development.

Rominger is a family farmer who worked with his brother, sons and nephews to raise alfalfa, beans, corn, rice, safflower, sunflowers, tomatoes, wheat and other crops in California. He served in government as director of the California Department of Food and Agriculture from 1977 to 1982. During that period, he served terms as president of the Western Association of State Departments of Agriculture and the Western U.S. Agricultural Trade Association. He also was on the board of directors for the National Association of State Departments of Agriculture.

Rominger was on the board of directors of American Farmland Trust from 1986 to 1993. He is active in a number of professional agricultural organizations concerned with soil and water policy, education, research and development and marketing.

He was selected Agriculturalist of the Year at the California State Fair in 1992, and throughout his career he has received numerous other awards including the Distinguished Service Award by the California Farm Bureau Federation in 1991.

Born in Woodland, Calif., Rominger received a Bachelor of Science Degree in plant science from the University of California at Davis. He is married to the former Evelynne Rowe. They have four children, Rick, Charlie, Ruth and Bruce.

#

February 1994

BIOGRAPHICAL SKETCH

TERRY L. MEDLEY, J.D.

As of February 28, 1994, Mr. Medley was detailed to the Food Safety and Inspection Service (FSIS) as the interim Acting Administrator. Since February 5, 1993, Mr. Medley has served as the Acting Associate Administrator of APHIS. In addition, he is the Director of the Biotechnology, Biologics, and Environmental Protection (BBEP) unit. As Director of the BBEP unit, Mr. Medley oversees and directs the activities of the National Monitoring and Residue Analysis Laboratory; Biotechnology Coordination and Technical Assistance; Veterinary Biologics; Veterinary Biologics Field Office; Biotechnology Permits; Environmental Analysis and Documentation; and the Technology Support Staff. These staffs are responsible for coordinating biotechnology regulatory activities within USDA and acting as liaison between USDA and other Federal Agencies on matters pertaining to biotechnology regulation; issuing permits for genetically engineered organisms; regulating and licensing veterinary biological products; providing internal policies and procedures for pesticide registration; conducting chemical analysis for pesticide residues; and ensuring that APHIS programs comply with the applicable environmental laws. Previously, he served as the Director for the Biotechnology and Environmental Coordination Staff of APHIS. He was born in Union, South Carolina, on September 12, 1951. Mr. Medley graduated cum laude from Amherst College in 1974. He earned a Doctor of Jurisprudence degree from the University of Virginia School of Law in 1977 and was elected to the Raven Society for his scholastic achievement and service to the community. Mr. Medley is a member of the Virginia Bar Association.

Upon graduation from law school, he began his Federal career as an attorney for the Regulation Division of USDA's Office of the General Counsel, providing legal services to APHIS and the Food Safety and Inspection Service (FSIS). In 1982, he was promoted to Senior Attorney and advisor for APHIS' Plant Protection and Quarantine programs. As part of the coordinated Federal effort to regulate biotechnology, he assisted in the drafting of the Federal "Coordinated Framework for Regulation of Biotechnology." He was an author of the USDA regulations for genetically engineered organisms that may be plant pests. He is a member of the Federal Biotechnology Research Subcommittee, Chair of the USDA Biotechnology Council, APHIS' liaison to the Agricultural Biotechnology Research Advisory Committee, and served as a member of the National Keystone Advisory Board for Biotechnology. He currently represents APHIS at the Organization for Economic Cooperation and Development meetings of the Joint Working Party for Environment and Agriculture and national experts on safety in biotechnology. He is Chairman of the Biotechnology ad hoc Committee of the North American Plant Protection Organization, member of the Biotechnology Advisory Commission of the Stockholm Environment Institute, and Agency Environmental Compliance Coordinator.

He is a frequent speaker-participant at biotechnology and environmental conferences in the United States and abroad and his papers have been published in numerous proceedings. He has received the USDA's Award for Superior Service from the Secretary of Agriculture for Outstanding Leadership in the Development and Implementation of Biotechnology Regulatory Policy on Behalf of APHIS and USDA; the USDA's Federal Women Interagency Boards' Achievement Award for Outstanding Contributions to the Federal Women's Program, and the USDA Office of Advocacy and Enterprise Partnership Award. Mr. Medley currently resides in Arlington, Virginia, with his wife Gerre and their two children.

JOHN GOLDENBusiness Address

U.S. Department of Agriculture
Office of the General Counsel
Room 2044-S, Washington, DC 20250
(202) 720-3155

Home Address

2221 Observatory Place, N.W.
Washington, D.C. 20007
(202) 965-3636

Education

Cornell University, Ithaca, New York
M.A. and Ph.D. in English Language and Literature, 1970.

The Cornell Law School, Ithaca, New York
J.D. in International Legal Studies, 1966.

Seton Hall University, South Orange, New Jersey
A.B. in Classical Languages, magna cum laude, 1963.

Experience

Associate General Counsel, U.S. Department of Agriculture,
1983-present.

Member, Administrative Conference of the United States,
1983-present.
Chairman, ACUS Committee on Regulation, 1989-present.

Civil Aeronautics Board: various positions including
Executive Assistant to Chairman, and Director, Bureau of
Compliance and Consumer Protection, 1974-83.

Private legal practice, Jersey City, New Jersey, 1972-74.

Assistant Professor of English, Purdue University, 1970-72.

Achievements

Member of the New Jersey Bar (1966) and the D.C. Bar (1976).

Phi Beta Kappa

Senior Executive Service, 1979-present.

Presidential Rank Award - Meritorious Executive, 1990.

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio

Bernard Sanders, Vermont
Independent

Majority (202) 225-2548
FAX (202) 225-2382
Minority (202) 225-2738

August 3, 1994

The Honorable Richard Lyng
829 Brady Ave.
Modesto, CA 95354

Dear Mr. Lyng:

In the exercise of oversight responsibilities pursuant to Rules X and XI of the House of Representatives, the Subcommittees on Human Resources and Intergovernmental Relations and Information, Justice, Transportation, and Agriculture of the House Committee on Government Operations jointly conducted a hearing on June 16, 1994, on the U.S. Department of Agriculture's (USDA) regulation and labeling of poultry products. The subcommittees focused on the basis and process for the Food Safety Inspection Services' (FSIS) Policy Memos 022B and 022C issued on July 11, 1988 and January 11, 1989, respectively (see attached).

At that hearing, Mr. Richard Rominger, Deputy Secretary, and other USDA officials, testified that they could not answer questions about the development and issuance of Policy Memos 022B and 022C because those memos were developed and issued during your tenure as Secretary of the Department of Agriculture.

At Rep. Horn's suggestion, we are writing to you in an attempt to determine the basis and process for FSIS's policy memos concerning the labeling of "fresh" poultry. Therefore, we would appreciate receiving your written responses to the attached questions on or before August 24, 1994.

Thank you in advance for your cooperation. Please contact Bill Layden of the subcommittee staff at (202) 225-2548 if you have any questions.

Sincerely,



Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations

Attachments

cc: The Honorable Steven Schiff
(Ranking Minority Member)

ATTACHMENT I

ATTACHMENT I

QUESTIONS FOR RICHARD LYNQ, FORMER SECRETARY OF AGRICULTURE

1. USDA/FSIS Policy Memo 022B, dated July 11, 1988, provided, in part, "The word 'fresh' may not be used in conjunction with the product name of: 3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location)."

-- What was your involvement in the development and issuance of this policy memo? Did you concur on the revision?

-- According to a signed declaration by Dr. Lester Crawford, former Administrator, FSIS, dated February 24, 1994, in 1988 Perdue Farms, Inc., requested FSIS to investigate the labeling of poultry as fresh. In an interview with subcommittee staff, Dr. Crawford stated that in a meeting with Frank Perdue of Perdue Farms, Inc. and Dr. Gillis of your staff, Mr. Perdue asked FSIS to review its policy for labeling "fresh" poultry. Dr. Crawford also stated that he and you met briefly with Mr. Perdue on the same issue. At the June 16, 1994 hearing, Dr. Crawford testified under oath that it was he and not you that decided to revise Policy Memo 022A.

Did you personally meet with Frank Perdue or any other member or representative of the poultry industry regarding the need to revise Policy Memo 022A and/or on the development and issuance of Policy Memo 022B? If yes, with whom did you meet and when?

-- Did you meet with any consumer groups, state representatives, members of the Congress, or officials from the White House regarding the need to revise Policy Memo 022A and/or on the development and issuance of Policy Memo 022B? If yes, with whom did you meet and when?

-- Did you instruct Dr. Crawford or any other member of your staff to revise Policy Memo 022A? If yes, what were your instructions and to whom did you give them?

-- What was the basis for establishing 26 degrees Fahrenheit as the threshold for "fresh" labeling?

2. On January 11, 1989, USDA/FSIS issued Policy Memo 022C that superseded Policy Memo 022B and stated, in part, "The word 'fresh' may not be used in conjunction with the product name of: 3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit."

-- What was your involvement in the development and issuance of this policy memo? Did you concur on the revision?

ATTACHMENT I

ATTACHMENT I

- Who was responsible for issuing Policy Memo 022C?
 - What was the basis for revising Policy Memo 022B?
3. According to Dr. Crawford's declaration, "After the issuance of Policy Memo 022B, representatives of the poultry industry approached the Secretary of Agriculture Richard Lyng and me. Secretary Lyng and I had two meetings with certain members of the National Broiler Council (NBC), including Holly Farms and Marshall Durbin, who differed with the conclusions stated in Policy Memo 022B." Dr. Kenneth May, representing the National Broiler Council, testified at the June 16, 1994 hearing that he recalled participating in at least one meeting with you on the need to revise Policy Memo 022B. Furthermore, according to a letter from Donald W. Mabe, President/CEO, Perdue Farms, Inc., Mr. Mabe met with you and Dr. Crawford on October 19, 1988 on the "fresh" vs. "frozen" labeling of poultry and poultry products.
- Following the issuance of Policy Memo 022B on July 11, 1989, did you personally meet with Dr. Kenneth May, Mr. Donald W. Mabe, Mr. Don Tyson or any other member or representative of the poultry industry on the policy memo? If yes, with whom did you meet, when, where and what was discussed on each occasion?
 - Following the issuance of Policy Memo 022B on July 11, 1989, did you meet with any consumer groups, state representatives, members of the Congress, or officials from the White House on the policy memo? If yes, with whom did you meet, when, where and what was discussed on each occasion?
4. According to a declaration by Dr. Lester Crawford, former administrator, FSIS, "Secretary Lyng instructed me to meet with members of the NBC [National Broiler Council] to resolve the issue. Secretary Lyng told me to work with the NBC members and to develop an acceptable accommodation."
- Specifically, what did you instruct Dr. Crawford to do?
 - What did you mean by "an acceptable accommodation?"
5. According to a January 9, 1991, letter from Ashland Clemons, Director, Standards and Labeling Division, FSIS, to Ms. Rosemary Mucklow, Western States Meat Association, "Since Policy Memo 022B would have dramatically changed traditional and longstanding practices of the poultry industry and since opposing views were so passionately expressed, the issue upon appeal reached the Secretary's office. There it was decided that the marketplace was best suited to decide if any further changes were necessary."

ATTACHMENT I

ATTACHMENT I

According to documents obtained by the subcommittees from USDA, you had instructed your staff to prepare a reply for your signature to a November 22, 1988 letter from Donald W. Mabe, President/CEO, Perdue Farms, Inc., that asked you to implement Policy Memo 022B without considering any changes for a six-month trial period. Drafts of the reply letter up until December 8, 1988, appeared to respond in a manner supporting Policy Memo 022B. Then, on December 21, 1988, Ronald J. Prucha, Associate Administrator, FSIS, sent a reply letter to Donald W. Mabe on your behalf. That letter announced that Policy Memo 022B would be revised and expressed the position that ultimately became Policy Memo 022C.

- Did you personally direct the position expressed in Policy Memo 022C? If yes, why?
 - What happened between December 8, 1988 and December 21, 1988 that caused you to change the Department's policy?
 - Who specifically was involved in the decision to revise Policy Memo 022B and issue Policy Memo 022C?
6. According to Dr. Crawford's declaration, "The change from 26 to zero degrees Fahrenheit was made as a political compromise."
 - Do you agree with Dr. Crawford's statement? If not, why?
 - Did USDA revise its policy on the labeling of "fresh" poultry only as a result of pressure from certain segments of the poultry industry? Please explain.
 7. Was Policy Memo 022B ever implemented or enforced? If not, why not?
 8. In your view, is Policy Memo 022C a sound policy? If yes, why?
 9. Have you been involved, in any way, on the issue of labeling "fresh" poultry since your departure from USDA? If yes, please explain.
 10. During your tenure as Secretary of Agriculture did you ever accept any free meals, transportation (e.g., air travel), lodging, entertainment (e.g., tickets to sporting events), or other gifts even of nominal value from any member, representative or agent of the meat and poultry industry? If yes, what did you accept, when, and from whom? During any of these occasions did you discuss the issue of labeling "fresh" poultry with members of the poultry industry?

JUL 11 1988

P.3




United States
Department of
Agriculture

Food Safety
and Inspection
Service

JUL 11 1988

To: Branch Chiefs, SLD

Policy Memo 0228

From: 
Ashland L. Clemons
Acting Director
Standards and Labeling Division, TS

Subject: Use of the Term "Fresh" on Meat and Poultry Products

ISSUE: Under what conditions may the term "fresh" be used on approved labeling of meat and poultry products?

POLICY: This policy memo supersedes Policy Memo 022A. The word "fresh" may not be used in conjunction with the product name of:

1. Any cured product, e.g., corned beef, smoked cured turkey, and prosciutto.
2. Any canned, hermetically sealed shelf stable, dried, or chemically preserved product.
3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location).

Generally, trademarks, company names, fanciful names, etc., containing the word "fresh" are acceptable, even on products produced in a manner described in 1, 2, or 3 above, provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh.

Further processed meat and poultry products, such as nuggets, dinners, etc., sold in the refrigerated state, may be labeled as "fresh" even when made from components processed in a manner described in 1, 2, or 3 above.

Labeling not in compliance with the provisions of this policy memo should be modified as soon as possible, but no later than 6 months from the date of this memo.

RATIONALE: This policy memo is issued for the purpose of defining and further clarifying the use of the term "fresh" on approved labeling of meat and poultry products. Historically, from a regulatory point of view, the term "fresh" has been used to describe red meats that have not been cured and raw poultry carcasses and parts that have not been previously frozen. Other uses of the

Branch Chiefs, SLD

2

term have never been clearly defined. This policy memo is an attempt to merge the traditional definition of "fresh" with new consumer perceptions that have developed because of the emergence of new products and the innovative technologies designed to produce and market these products.

In an effort to standardize the requirements for red meat and poultry products, we will no longer allow poultry products which are cured to include the term "fresh" in conjunction with the product name. The regulations (9 CFR 317.8 (b) (6)) presently do not allow cured red meat products to be labeled as "fresh," and we do not believe that there is a valid reason to differentiate cured red meats from cured poultry products. The absence of a similar provision in the poultry regulations is apparently due to the fact that such poultry products were not available at the time the regulations were written.

Products which are canned, hermetically sealed and shelf stable, dried, or chemically preserved, cannot be labeled to include "fresh" in conjunction with the product name since such a use would be inappropriate and misleading.

"Fresh" will continue to be restricted from use in conjunction with the product name on frozen or previously frozen unprocessed poultry. Unlike red meat products, the term "fresh" on poultry, poultry parts, and other edible portions, has acquired marketing significance and offers a meaningful distinction to purchasers between frozen and never frozen products.

"Fresh" may be used on processed products containing ingredients that could not be labeled "fresh" since the term has acquired acceptance when used to identify products sold in the refrigerated state. An example would be a pepperoni pizza or ham salad sold in the refrigerated section of a market. Other products that fall into this category are those in hermetically sealed packages, e.g., vacuum packed meat, which are designed to assure freshness but are not shelf stable and are sold in the refrigerated state. We also recognize that, in many instances, the word "fresh" could be incorporated into the firm name or brand name and used on cured, preserved, and frozen or previously frozen poultry products where it would be highly unlikely that the consumer would be led to believe that he or she was purchasing a fresh product.



05/19/94 14:54
UNITED STATES
Department of
Agriculture

202 720 2025
FOOD SAFETY
and Inspection
Service


USDA FSIS RP

002/003

JAN 11 1989

Branch Chiefs, SLD

Policy Memo 022C


Ashland L. Clemons, Acting Director
Standards and Labeling Division
Technical Services

Subject: Use of the Term "Fresh" on Meat and Poultry Products

ISSUE: Under what conditions may the term "fresh" be used on approved labeling of meat and poultry products?

POLICY: This policy memo supersedes Policy Memo 022B. The word "fresh" may not be used in conjunction with the product name of:

1. Any cured product, e.g., corned beef, smoked cured turkey, and prosciutto.
2. Any canned, hermetically sealed shelf stable, dried, or chemically preserved product.
3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit.

Generally, trademarks, company names, fanciful names, etc., containing the word "fresh" are acceptable, even on products produced in a manner described in 1, 2, or 3 above, provided the term is used in such a manner that it remains clear to the purchaser that the product is not fresh.

Further processed meat and poultry products, such as nuggets, dinners, etc., sold in the refrigerated state, may be labeled as "fresh" even when made from components processed in a manner described in 1, 2, or 3 above.

Since there are no anticipated labeling changes necessary as a result of the modifications made in this policy memo, the January 11, 1989, date set in Policy Memo 022B for compliance with these provisions is still in effect.

RATIONALE: This policy memo is issued for the purpose of defining and further clarifying the use of the term "fresh" on approved labeling of meat and poultry products. Historically, from a regulatory point of view, the term "fresh" has been used to describe red meats that have not been cured and raw poultry carcasses and parts that have not been previously frozen.

Other uses of the term have never been clearly defined. This policy memo is an attempt to merge the traditional definition of "fresh" with new consumer perceptions that have developed because of the emergence of new products and the innovative technologies designed to produce and market these products.

In an effort to standardize the requirements for red meat and poultry products, we will no longer allow poultry products which are cured to include the term "fresh" in conjunction with the product name. The regulations (9 CFR 317.8(b)(6)) presently do not allow cured red meat products to be labeled as "fresh," and we do not believe that there is a valid reason to differentiate cured red meats from cured poultry products. The absence of a similar provision in the poultry regulations is apparently due to the fact that such poultry products were not available at the time the regulations were written.

Products which are canned, hermetically sealed and shelf stable, dried, or chemically preserved cannot be labeled to include "fresh" in conjunction with the product name since such a use would be inappropriate and misleading.

Policy Memo 022B is being revised to reflect the deletion of the provision that established 26 degrees Fahrenheit (or less) as the threshold temperature at which unprocessed poultry products could not be labeled as "fresh." The Agency has now decided, after much deliberation on this issue, not to limit the use of the term "fresh" on unprocessed poultry products based on an internal temperature with the exception as defined by the current regulations, i.e., product is above zero degrees and below 40 degrees Fahrenheit, and has not been previously frozen at or below zero degrees Fahrenheit. This decision is predicated on the belief that it is not practical under existing marketing strategies and distribution patterns, to define "fresh" in terms of internal temperature beyond the scope of the current regulations, nor is it practical to define consumer expectations for poultry products labeled as "fresh." The consumer is the best judge of preference in chilling temperatures for unprocessed poultry products labeled as "fresh," and therefore the marketplace is best suited for making this type of decision.

"Fresh" may be used on processed products containing ingredients that could not be labeled "fresh" since the term has acquired acceptance when used to identify products sold in the refrigerated state. An example would be a pepperoni pizza or ham salad sold in the refrigerated section of a market. Other products that fall into this category are those in sealed packages or containers, (e.g., vacuum packed meat and the newer thermoformed oxygen barrier multilayer films), which are designed to assure freshness but are not shelf stable and are sold in the refrigerated state. We also recognize that, in many instances, the word "fresh" could be incorporated into the firm name or brand name and used on cured, preserved, and frozen or previously frozen poultry products where it would be highly unlikely that the consumer would be led to believe that he or she was purchasing a fresh product.

RICHARD E. LYN
829 BRADY AVE.
MODESTO, CALIFORNIA
95354

August 19, 1994

Hon. Adolphus Towns
Chairman, Subcommittee on Human Resources
B 372 Rayburn House Office Building
Washington D.C. 20515

Dear Mr. Chairman:

This letter is in response to your letter to me of August 3, 1994.

Sincerely,



Enclosed; 6 pages Questions and answers

ATTACHMENT I

ATTACHMENT I

QUESTIONS FOR RICHARD LYNG, FORMER SECRETARY OF AGRICULTURE

1. USDA/FSIS Policy Memo 022B, dated July 11, 1988, provided, in part, "The word 'fresh' may not be used in conjunction with the product name of: 3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen to 26 degrees Fahrenheit or below (at its center or core location)."

-- What was your involvement in the development and issuance of this policy memo? Did you concur on the revision?

I was serving as Secretary of Agriculture at the time the Policy Memo was issued. I was aware of the issue and encouraged the executives of the ~~FSIS~~ FSIS to take some action. I think I concurred on the revision.

- According to a signed declaration by Dr. Lester Crawford, former Administrator, FSIS, dated February 24, 1994, in 1988 Perdue Farms, Inc., requested FSIS to investigate the labeling of poultry as fresh. In an interview with subcommittee staff, Dr. Crawford stated that in a meeting with Frank Perdue of Perdue Farms, Inc. and Dr. Gillis of your staff, Mr. Perdue asked FSIS to review its policy relating "fresh" poultry. Dr. Crawford also stated that he and you met with Mr. Perdue on the same issue. At the June 16, 1994 hearing, Dr. Crawford testified under oath that it was he and not you that agreed to revise Policy M.

Did you personally meet with Frank Perdue or any other member or representative of the poultry industry regarding the need to revise Policy Memo 022A and/or on the development and issuance of Policy Memo 022B? If yes, with whom did you meet and when?

I cannot remember the specific meeting described. I think I did meet with Perdue and with other members or representatives of the poultry industry. I cannot remember where or when such meeting took place.

2

Did you meet with any consumer groups, state representatives, members of the Congress, or officials from the White House regarding the need to revise Policy Memo 022A and/or on the development and issuance of Policy Memo 022B? If yes, with whom did you meet and when?

I cannot remember ^{any} ~~name~~ meetings.

Did you instruct Dr. Crawford or any other member of your staff to revise Policy Memo 022A? If yes, what were your instructions and to whom did you give them?

I think I did urge Dr. Crawford and Dr. Gills to revise the Policy Memo.

-- What was the basis for establishing 26 degrees Fahrenheit as the threshold for "fresh" labeling?

I can recall technicians on the FSIS staff saying that while water freezes at 32 degrees, poultry is different and actually freezes at about 26 degrees.

2. On January 11, 1989, USDA/FSIS issued Policy Memo 022C that superseded Policy Memo 022B and stated, in part, "The word 'fresh' may not be used in conjunction with the product name of: 3. Any poultry, poultry part, or any edible portion thereof that has been frozen or previously frozen at or below zero degrees Fahrenheit."

-- What was your involvement in the development and issuance of this policy memo? Did you concur on the revision?

2

I was not involved in any way.
I retired from U.S.D.A. ~~on January 10, 1989~~
~~on January 10, 1989~~

ATTACHMENT I

ATTACHMENT I

- Who was responsible for issuing Policy Memo 022C?
- What was the basis for revising Policy Memo 022B?

I do not know

3. According to Dr. Crawford's declaration, "After the issuance of Policy Memo 022B, representatives of the poultry industry approached the Secretary of Agriculture Richard Lyng and me. Secretary Lyng and I had two meetings with certain members of the National Broiler Council (NBC), including Holly Farms and Marshall Durbin, who differed with the conclusions stated in Policy Memo 022B." Dr. Kenneth May, representing the National Broiler Council, testified at the June 16, 1994 hearing that he recalled participating in at least one meeting with you on the need to revise Policy Memo 022B. Furthermore, according to a letter from Donald W. Mabe, President/CEO, Perdue Farms, Inc., Mr. Mabe met with you and Dr. Crawford on October 19, 1988 on the "fresh" vs. "frozen" labeling of poultry and poultry products.
- Following the issuance of Policy Memo 022B on July 11, 1989, did you personally meet with Dr. Kenneth May, Mr. Donald W. Mabe, Mr. Don Tyson or any other member or representative of the poultry industry on the policy memo? If yes, with whom did you meet, when, where and what was discussed on each occasion?

~~*I cannot recall such a meeting*~~

No. I was not Secretary of Agriculture on July 11, 1989

- Following the issuance of Policy Memo 022B on July 11, 1989, did you meet with any consumer groups, state representatives, members of the Congress, or officials from the White House on the policy memo? If yes, with whom did you meet, when, where and what was discussed on each occasion?

No. I was not Secretary of Agriculture on July 11, 1989

4

- .. What happened between December 8, 1988 and December 21, 1988 that caused you to change the Department's policy?

*I do not recall any of this. ~~Therefore~~
I left USDA ~~on Jan 20, 1989~~*

on Jan 20, 1989

- .. Who specifically was involved in the decision to revise Policy Memo 022B and issue Policy Memo 022C?

I do not know.

6. According to Dr. Crawford's declaration, "The change from 26 to zero degrees Fahrenheit was made as a political compromise."

- .. Do you agree with Dr. Crawford's statement? If not, why?

No, I disagree. But I really do not know what took place after I retired.

- .. Did USDA revise its policy on the labeling of "fresh" poultry only as a result of pressure from certain segments of the poultry industry? Please explain.

*I do not recall the policy revision.
If one took place I had absolutely nothing to do with it.*

7. Was Policy Memo 022B ever implemented or enforced? If not, why not?

I do not know.

8. In your view, is Policy Memo 022C a sound policy? If yes, why?

I do not know

9. Have you been involved, in any way, on the issue of labeling "fresh" poultry since your departure from USDA? If yes, please explain.

NO

4. According to a declaration by Dr. Lester Crawford, former administrator, FSIS, "Secretary Lyng instructed me to meet with members of the NBC [National Broiler Council] to resolve the issue. Secretary Lyng told me to work with the NBC members and to develop an acceptable accommodation."

-- Specifically, what did you instruct Dr. Crawford to do?

I urged him to develop a policy which would end the disagreement on the frozen poultry, which would be fair to everyone involved including consumers.

-- What did you mean by "an acceptable accommodation?"

5. According to a January 9, 1991, letter from Ashland Clemons, Director, Standards and Labeling Division, FSIS, to Ms. Rosemary Mucklow, Western States Meat Association, "Since Policy Memo 022B would have dramatically changed traditional and longstanding practices of the poultry industry and since opposing views were so passionately expressed, the issue upon appeal reached the Secretary's office. There it was decided that the marketplace was best suited to decide if any further changes were necessary."

3

ATTACHMENT I

ATTACHMENT I

According to documents obtained by the subcommittees from USDA, you had instructed your staff to prepare a reply for your signature to a November 27, 1988 letter from Donald W. Mahe, President/CEO, Perdue Farms, Inc., that asked you to implement Policy Memo 022B without considering any changes for a six-month trial period. Drafts of the reply letter up until December 8, 1988, appeared to respond in a manner supporting Policy Memo 022B. Then, on December 21, 1988, Ronald J. Prucha, Associate Administrator, FSIS, sent a reply letter to Donald W. Mahe on your behalf. That letter announced that Policy Memo 022B would be revised and expressed the position that ultimately became Policy Memo 022C.

-- Did you personally direct the position expressed in Policy Memo 022C? If yes, why?

*I do not recall any of this. I
left USDA around ~~December~~ 1989
on Jan 20, 1989.*

5

10. During your tenure as Secretary of Agriculture did you ever accept any free meals, transportation (e.g., air travel), lodging, entertainment (e.g., tickets to sporting events), or other gifts even of nominal value from any member, representative or agent of the meat and poultry industry? If yes, what did you accept, when, and from whom? During any of these occasions did you discuss the issue of labeling "fresh" poultry with members of the poultry industry?

4

NO

APPENDIX 8.—ADDITIONAL MATERIAL FOR THE SEPTEMBER 28, 1994, HEARING RECORD

Edolphus Towns, New York
Chairman
Henry A. Waxman, California
Thomas M. Barrett, Wisconsin
Donald M. Payne, New Jersey
Craig A. Washington, Texas

ONE HUNDRED THIRD CONGRESS
Congress of the United States
House of Representatives

Human Resources and Intergovernmental Relations
Subcommittee
of the
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, DC 20515

Steven Schiff, New Mexico
Ranking Minority Member
John L. Mica, Florida
Rob Portman, Ohio

Bernard Sanders, Vermont
Independent

Majority (202) 225-2548

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Minority (202) 225-2738

September 23, 1994



MEMORANDUM

TO: Members of the Subcommittee on Human Resources and
Intergovernmental Relations

FROM: Edolphus Towns, Chairman

RE: Hearing: "Reinventing the Federal Food Safety System: Chemical Residues
and Contaminants in Food," Wednesday, September 28, 1994, at 9:45 a.m.,
2247 RHOB

I. INTRODUCTION

As you know, the Subcommittee has been reviewing the Federal government's food safety programs in light of the Vice President's recommendation to consolidate such programs within the Food and Drug Administration (FDA). The Subcommittee's initial hearings on the U.S. Department of Agriculture's (USDA) meat and poultry inspection program last November 4 and 19 revealed dangerous flaws in USDA's programs and an inherent conflict of interest in USDA's mission (see my memoranda of Nov. 1 and Nov. 16). The subcommittee's hearing on FDA's food safety programs on May 25 revealed that FDA suffers from its own problems: inadequate resources and enforcement authority. The subcommittee's hearing on June 16 regarding the safety and labeling of "fresh" poultry revealed additional problems with USDA's programs.

Our previous hearings have also focused mostly on microbial contamination of food because food safety experts believe that to be the primary risk to consumers. This hearing is focused on chemical residues and contaminants in food which the public continues to be very concerned about.

II. BACKGROUND

A variety of chemical compounds have helped to improve both the quantity and quality of the Nation's food supply. At the same time, concerns remain about the human health implications of chemical compounds in food. Chemical residues in food may result from the intentional use of pesticides, animal drugs, and food additives in or on food, such as crops and livestock. Environmental contaminants (e.g., lead and mercury) in food may result from unintentional exposure of food sources to naturally occurring or

industrial pollutants.

Multiple Federal agencies are responsible for reviewing and approving the intentional use of chemicals in food, establishing acceptable limits of chemical compounds in food, and monitoring and enforcing these limits.

- Pesticides: The Environmental Protection Agency (EPA) registers (licenses) specific uses of individual pesticide products and sets tolerances (legal limits) on the amount of residues that may remain in/on food. USDA monitors meat and poultry products and FDA monitors all other food for excess residues (e.g., residue exceeds tolerance or no tolerance exists). FDA is responsible for taking enforcement action if excess residues are found.
- Animal drugs: FDA reviews and approves animal drugs and substances added to animal feed and sets tolerances on the amount of residues that may remain in food and feed. FDA and the states monitor the milk supply for drug residues and USDA monitors meat and poultry tissue. FDA is responsible for taking enforcement action if excess residues are found.
- Environmental contaminants: Because these substances are not intentionally added to food, no pre-market approval is required. USDA monitors meat and poultry and FDA monitors all other food. FDA is responsible for establishing safety limits for these compounds in food.

III. RELEVANT LAWS

Federal Insecticide, Fungicide, and Rodenticide Act, as amended
 Federal Food, Drug, and Cosmetic Act, as amended (FFDCA) (21 U.S.C. 301 et seq.)
 Federal Meat Inspection Act, as amended
 Poultry Products Inspection Act, as amended
 Egg Products Inspection Act
 (Other relevant laws include, the Public Health Service Act, Pesticide Monitoring Improvement Act of 1988, Safe Drinking Water Act, Federal Anti-Tampering Act, and Federal Import Milk Act)

IV. PURPOSE OF THE HEARING

The purpose of this hearing is to continue to review Federal food safety programs in light of the Vice President's recommendations to consolidate all Federal food safety programs within FDA. The hearing will focus on Federal efforts to ensure the safety of the Nation's food supply from unsafe and/or illegal chemical residues and contaminants.

We will be releasing two reports by the U.S. General Accounting Office (GAO) prepared at the subcommittee's request:

- Food Safety: USDA's Role Under the National Residue Program Should be Reevaluated (GAO/RCED-94-158), and
- Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192)

Both of these reports are in draft form and should not, under any circumstance, be released to anyone outside of the subcommittee.

V. WITNESSES

The subcommittee expects the following witnesses to present testimony:

Panel I

John Harman, Director, Food and Agriculture Issues, RCED/GAO

Panel II

Mike Taylor, Administrator, Food Safety Inspection Service, USDA

Panel III

Dr. Fred Shank, Director, Center for Food Safety and Applied Nutrition, FDA
 Dr. Steven Sundlof, Director, Center for Veterinary Medicine, FDA
 Dr. Lynn Goldman, Assistant Administrator for Prevention, Pesticides and Toxics, EPA
 Mike Taylor, Administrator, Food Safety Inspection Service, USDA (to participate in Q&A only on this panel)

VI. MAJOR ISSUES

The two GAO reports lay out the issues very well. The GAO report on USDA's residue program raises some real concerns about the weaknesses in USDA's programs to ensure the safety of imported meat and poultry and methodological flaws in USDA's program. The second GAO report identifies five structural weaknesses in the Federal government's programs to monitor chemicals in food:

- fragmented Federal agency responsibilities,
- inconsistent legal and regulatory infrastructure,
- resource-intensive and inefficient compliance monitoring system,
- inadequate enforcement system, and
- vulnerable import inspection programs.

GAO's reports document that the Federal government's current approach for monitoring chemical residues and contaminants--end-product testing--cannot ensure food safety. GAO recommends, among other things, that the Congress revise the nature of the Federal government's role for ensuring food safety by moving it away from end-product testing to preventing contamination from occurring. GAO believes that the Hazard Analysis Critical Control Point (HACCP) (see my earlier memos) approach could be used to achieve this fundamental change in the way the Federal government oversees the safety of the Nation's food supply.

The scope of this hearing is very broad and one could touch upon many, many program details and flaws that have already received widespread publicity and interest. Ultimately, however, the hearing is designed to examine how the Federal government can move to a more modern, cost-effective approach to ensure food safety. The witnesses that will be testifying have each inherited programs with known flaws. We need to hear from them how the Administration is planning to move to this new approach and what assistance the Congress can provide to facilitate and expedite this paradigm shift.

A Bowlful of Lessons

How a Pesticide Got Into Cheerios

By Sharon Walsh

Washington Post Staff Writer

Millions of children and adults ate their Cheerios over the past several months with bananas or blueberries, sugar or honey, whole or skim milk, and an unexpected, added ingredient—an illegal pesticide.

The Food and Drug Administration and the Environmental Protection Agency have determined that the chemical, chlorpyrifos-ethyl, which had been sprayed on oats used to make 16 popular General Mills Inc. cereals, did not pose a public health risk. The chemical is approved for and widely used on other food products, such as apples, bananas, beans and wheat in the fields. But approval has not been sought for its use on stored grains.

This Cheerios story shows how popular food products that have been adulterated can escape detection and reach millions of consumers. General Mills said 110 million boxes of its cereals made with the illegally sprayed oats were sold because of a tear in the food safety net that worries government officials responsible for protecting the food supply.

Even if the pesticide had been deadly, instead of illegal but safe, it probably would not have been caught before it appeared on grocers' shelves, according to food safety experts.

"It's one of the nightmares I have," said L. Robert Lake, director of policy and planning for the Center for Food Safety and Applied Nutrition at FDA. "It could easily have been a more toxic chemical."

Equally troubling is the question of how the actions of one man went undetected by General Mills, a food industry giant with sales last year of \$8.52 billion and a good reputation for safety. The company, which spent \$258 million last year on quality control, did not test for pesticide residues in its cereal because "we have never had a problem with pesticide residue," said spokesman Austin Sullivan.

Y. George Roggy, a subcontractor of General Mills, was charged last week in Minnesota with knowingly misusing the pesticide, called Dursban commercially. Dursban was cheaper than a similar one approved for use on oats, and Roggy allegedly saved \$85,319 by using it for about a year and billing General Mills for the more expensive, legal chemical.

Prosecutors in Minnesota said their investigation is continuing and General Mills is cooperating.

"The basic responsibility [for food safety] is really with the industry... with the growers and applicators and food companies," said Lake. "One of the things bothersome to us about the General Mills incident is it went on for an extended period of time and they didn't know. It means they didn't have a good system for checking oats."

Said General Mills Vice Chairman Joe R. Lee: "We make great efforts to make our products nutritious, safe and wholesome. In this case, it didn't work.... Fortunately, it had no safety impact."

FDA's monitoring of the food supply for illegal pesticides is, at best, random, said Lake and others. In fact, it was nothing short of a miracle that the Dursban was found in the General Mills oat supply at all.

This account of how the pesticide was discovered and decisions made about how to respond was compiled from interviews with more than a dozen officials of the FDA, EPA and the office of the Minnesota Agriculture Commissioner.

The FDA is responsible for monitoring the food supply for pesticide residues and acts as regulator. The EPA registers pesticides and determines what they can be used for.

General Mills provided some information, although the company refused to let a reporter visit its cereal-making facilities in Minneapolis and declined to make its food safety experts available.

On May 11 and 12, FDA field agents from the Kansas City district collected routine samples of oats from grain elevators in Des Moines. Nearly a month went by while the samples were analyzed by the FDA regional lab in Dallas, the findings communicated to the Kansas City, Kan., office, and the source of the Des Moines oats traced to General Mills, known in its home town of Minneapolis as "Big G."

Dursban, widely used in a host of products, including flea powders for dogs and cats and indoor pest sprays for spiders, ticks and termites, is not approved for use on any stored grains.

When further tests confirmed that General Mills' oats had been sprayed with the pesticide, alarm bells started going off. The company was notified by fax and telephone of the FDA's finding on Friday, June 10.

"We were surprised," said Sullivan. "Our reaction was that we don't use that chemical."

The company immediately stopped using oats and oat flour and cut off distribution of all its oat products. Toxicologists began testing the company's oats. By Saturday morning, officials of the company said, they were 95 percent certain there were no health dangers to the public from the pesticide residue.

On Sunday, June 12, three General Mills officials, including the company's director of security, interviewed Roggy, who admitted he had used Dursban for about 13 months instead of its approved chemical cousin, chlorpyrifos-methyl (known commercially as Rel-dan), because he had financial difficulties and Dursban was cheaper.

Asked what kind of agreement Roggy, head of Fumcon Inc., had with the company, Sullivan replied that he didn't think there was a written contract. "He was just somebody we used from time to time," he said.

Roggy, licensed by Minnesota to spray pesticides, worked without supervision, spraying oats as they came off ships into General Mills' grain storage elevators in Duluth, Minn., and Superior, Wis. Not all of the company's oats were sprayed—only those that were going into long-term storage in anticipation of the days when the Great Lakes would freeze and ships would be unable to deliver their cargo.

Still, Roggy managed to spray Dursban on 16.8 million bushels of oats, some of which the company used to make 160 million boxes of breakfast cereals such as Cheerios, Lucky Charms, Boobyerry and Trix. Most of the cereals made from oats sprayed with Dursban were shipped to grocery stores in March. By the time the company found out about the illegal spraying, 110 million boxes were on the shelves in grocery stores and consumers' homes.

"Normally, when there's a foul-up on food production, it's caught much earlier in the game," said FDA's Lake. "Usually the company discovers it and initiates a recall on its own.... But the magnitude of this was much larger than anything else we'd seen.... People had already fed it to their children."

G. REC-92-205 7/14/92, 144096-102, 9/10/92

—Paul & Nancy

Cheerios are often one of the first solid foods eaten by children, and are favored by parents and pediatricians because they are easy to swallow and not heavily sugared like some cereals.

And the product is ubiquitous. Virtually every federal official who talked about the case mentioned that his or her children eat Cheerios. When a group of parents recently filed a class-action suit in Chicago against General Mills for consumer fraud because of the pesticide use, Judge Dorothy Kirie Kinnaird recused herself, saying she and her family eat Cheerios all the time and she couldn't be unbiased in such a case.

On Monday, June 13, EPA and FDA officials in Washington began to address the question of whether they had a public health emergency on their hands.

"Our first concern was: Do we need to do something about the Cheerios people already have?" said Dr. Lynn Goldman, assistant administrator for prevention, pesticides and toxic substances at EPA. "We didn't want to raise an alarm for no good reason and scare people, but we didn't want to fail to warn them either."

Both agencies immediately asked the company for the results of its tests. How much of the pesticide residue was present in the cereal? In addition, the agencies' scientists did their own tests, buying about 200 boxes of cereal off grocers' shelves around the country.

"Virtually all the samples but one were okay," said Stephen L. Johnson, the EPA's director of pesticide registration. "We didn't believe there would be any harmful effects to people."

Johnson said that in much, much greater levels of residue, Dursaban could cause headaches, nausea, vomiting, diarrhea and loss of balance.

The two government agencies decided not to press the company to recall the cereal. "We were concerned that a recall would have been very disturbing to parents who had already fed their children Cheerios," said Lake. "We didn't want to cause a public panic."

On Wednesday, June 15, after three days of intense meetings and consultations between the government and the company, FDA alerted news organizations that the oat products had been sprayed with chlorpyrifos-ethyl, but that the oats "do not present a health hazard."

The company notified grocers, who continued to sell the products.

The company had stopped production while it brought in a new supply of oats, but once it resumed making cereal it found there was still pesticide residue in its equipment.

"We shut down the plants and literally disassembled the machinery to get it out of every nook and cranny," said Sullivan. As a result, many grocery stores, including some in the Washington area, have run out of affected brands.

But there was another question. General Mills had on hand an additional 50 million boxes of cereal made from oats that had been sprayed with Dursaban. It also had about 15 million bushels of oats remaining that had been sprayed. The company had decided that it would not use the raw oats for human food. But since regulators had found no health hazard from the chemical, would FDA agree to let the company sell the 50 million boxes of cereal?

"We didn't want to send a signal to the company that it's okay to violate the law as long as it doesn't hurt anybody," said Lake. In addition, FDA was worried that foreign countries that ship grains to the United States would expect the same treatment as General Mills.

"So we had to say no," he said.

The company was told it could apply for a temporary approval of the use of Dursaban on oats from the EPA. After submitting the petition, however, General Mills found that the process would take so long that even if it was approved, "the cereal would have been out of date. It would have been stale," said Sullivan.

Several organizations contacted the government about the possibility of sending the cereal to help feed Rwanda's hungry children. The idea was determined to be impractical: Cereal is low-density nutrition, expensive to ship. In addition, "we would not have wanted to pick up the paper and read: 'Poison Cereal Dropped on Rwanda,'" said Lake.

The idea was abandoned.

General Mills will take a write-off against earnings of as much as \$87.5 million because of the Dursaban appli-

cation, according to Sullivan. The company is currently disposing of 50 million boxes of Cheerios in landfills and incinerators under the watchful eye of the Minnesota office of the FDA. It is working with the EPA on the question of whether the 15 million bushels of sprayed oats it still has can be used as animal feed.

The company has revised its safety procedures at the FDA's request. Among the changes: Raw oats are now regularly tested for pesticides; General Mills will provide contractors with pesticides and monitor their work; it will expand its lab facilities and add a new grain quality manager.

Roggy, who has pleaded not guilty to criminal charges, faces a criminal trial and a sentence of up to eight years in prison if convicted. In addition, Minnesota has called for a hearing to review his license to spray pesticides and may bring its own criminal or civil charges.

"There is one thing that the government, General Mills and Mr. Roggy all agree on," said John W. Lundquist, Roggy's attorney. "The product was completely safe. . . . The problem is it doesn't appear on the government's list of approved pesticides. The dispute is over whether that justifies the prosecution of an individual and the dumping of millions of bushels of oats."

Meanwhile, the company believes the supply of cereal made from oats sprayed with Dursaban is virtually out of the pipeline, though some rural stores may still have some on their shelves.

General Mills has "a very good [safety] program, one of the best in the industry," said Lee, the company's vice chairman. "It still didn't catch . . . someone who willfully lied about what he was using. . . . We have great confidence that now we'd catch it."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

June 15, 1994

FDA Press Office: 202-205-4144

PESTICIDE MISUSE DETECTED

The unapproved use by an outside contractor of a pesticide, chlorpyrifos, on oats used by General Mills, Inc., was detected during routine pesticide surveillance by the Food and Drug Administration (FDA). Chlorpyrifos is approved for use on numerous other foods. A nearly identical pesticide, chlorpyrifos methyl, is approved for use on oats.

- A preliminary review by toxicologists from the FDA and the U.S. Environmental Protection Agency indicates that the oat products on the market containing chlorpyrifos residues do not present a health hazard. The agencies will continue their investigation, as well as initiate any appropriate actions.

Under the pesticide statutes, EPA reviews the safety of pesticides and grants registrations for their use, and the FDA enforces the tolerances for pesticide residues on food that are set as part of the EPA registration process.

###

July 7, 1994

Desk Statement on Chlorpyrifos

(For use by EPA HQ and Regions in Responding to Public Inquiries)

On June 13, 1994, EPA was notified by the Food and Drug Administration that it found residues of the pesticide chlorpyrifos on oat products from General Mills, Inc. Chlorpyrifos is not approved for use on oat products. General Mills has stated that these residues resulted from the unapproved use of chlorpyrifos by an outside contractor. A chemically-similar pesticide, chlorpyrifos-methyl, is approved for use on oat products.

In response, EPA immediately performed an evaluation to assess the potential dietary risk to humans from consumption of the oat products containing chlorpyrifos residues. The information available to EPA at that time indicated that consumption of oat products containing the low levels of chlorpyrifos detected did not present a human health hazard.

When EPA registers pesticides to be used on foods, a tolerance (maximum amount of pesticide residue) must be established. To assure that the tolerance-setting procedures are protective of human health, EPA requires extensive information about the anticipated amount of pesticide residues found on food, the toxic effects of these residues and estimates of the types and amounts of foods that make up our diet. Typically, this review process takes several months and provides an opportunity for public involvement.

Although General Mills initially submitted a "time-limited tolerance" petition to allow the distribution and sale of cereal products made from oats that were previously treated with chlorpyrifos, they later asked EPA to place a hold on their petition. Therefore, EPA is not evaluating a tolerance petition at this time.



Questions & Answers

Unapproved Use Of Chlorpyrifos On Oats

The Food and Drug Administration recently found low levels of the pesticide chlorpyrifos on oat products from General Mills, Inc. Chlorpyrifos is not approved for use on oat products. General Mills has stated that these residues resulted from the unapproved use of chlorpyrifos by an outside contractor. A chemically-similar pesticide, chlorpyrifos-methyl, is approved for use on oat products.

What are chlorpyrifos and chlorpyrifos-methyl?

Chlorpyrifos is a broad-spectrum, organophosphate insecticide used on a wide variety of food crops as a pre-harvest treatment (while actively growing in the field), turf and ornamental plants, indoor and structural pest control, and pet products. Chlorpyrifos is not, however, approved for use on oats. The primary manufacturers are Dow Elanco and Makhteshim-Agan. It was first registered in 1965.

Chlorpyrifos-methyl is chemically similar to chlorpyrifos and is also used as an insecticide. It is registered only for use on stored grains, including oats, after they have been harvested.

What General Mills cereals contain oats which have been found to contain chlorpyrifos residues?

The following General Mills cereals have been found to contain low levels of chlorpyrifos residues: Cheerios, Apple Cinnamon Cheerios, Lucky Charms, Honey Nut Cheerios, and Multi Grain Cheerios. To date, residues have not been found in the following oat products: Oatmeal Raisin Crisp, Kix, Basic 4, Trix, Reese's Peanut Butter Puffs, and Berry Berry Kix. Sampling of oat products by FDA and the firm will continue.

Is it safe to continue to eat General Mills oat cereals?

The information available to FDA and EPA indicates that consumption of oat products containing the low levels of chlorpyrifos detected does not present a health hazard.

What are the potential health effects of exposure to high levels of chlorpyrifos?

Short-term exposure to high levels of chlorpyrifos, an organophosphate, may affect the nervous system by inhibiting the activity of an enzyme called cholinesterase. These effects would be expected to occur only at levels much higher than those that have been detected in the General Mills oat products.

Cholinesterase normally breaks down acetylcholine which helps transmit signals through the nervous system. When cholinesterase is inhibited, an excess of acetylcholine builds up and impairs the proper functioning of the nervous system. Inhibition resulting from exposure to chlorpyrifos is slowly reversible.

Signs and symptoms of exposure to high levels of chlorpyrifos may be headache, dizziness, loss of coordination, muscle twitching, tremor, nausea, vomiting, abdominal cramps, diarrhea and general weakness.

How was this contamination first detected and what is the current status of the investigation?

In May 1994, FDA sampled oats at two Iowa feed distributors and reported a preliminary finding of chlorpyrifos to EPA's Kansas City Office on May 25. EPA then notified the State of Iowa, which conducted a pesticide use investigation at the distributors. The investigation did not reveal chlorpyrifos misuse at the feed distributors. Consequently, the State provided FDA with documentation identifying the oat supplier as General Mills, a potential source of pesticide contamination. FDA's follow-up investigation at General Mills disclosed that the source of contamination was the treatment of oats at the grain elevator.

On June 13, 1994, FDA notified EPA of the misapplication of chlorpyrifos to approximately 21 million bushels of stored oats at General Mills. Of these 21 million bushels, 4 million had been processed into General Mills cereal products and 15 million bushels are currently being held by the company. Although chlorpyrifos has been registered by EPA for treatment of a number of agricultural crops, it has not been registered for use on oats. The oats were treated by a commercial applicator under contract to General Mills.

EPA is cooperating with the Minnesota Department of Agriculture in its investigation to determine the extent of commodity contamination and development of an appropriate corrective action plan and enforcement response.

Pesticides are regulated by EPA pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Act requires that registered pesticides be used in accordance with label directions. The Act further provides that states shall have primacy for investigating and enforcing violations involving pesticide misuse.

Are there oat products other than those sold by General Mills that contain chlorpyrifos residues?

At this point, the Agency is unaware of any additional oat products that may contain chlorpyrifos residues. However, the Agency, in cooperation with FDA and State agencies, will continue its investigation, and will initiate any appropriate actions.

Why are pesticides used on stored grains, including oats?

Pesticides may be applied to grains to protect them during storage against injury from many insects including grain weevils, moths, borers, beetles, and mealworms.

MARKETPLACE

Cereals With Pesticide Were in Stores for a Year

By Richard Gamow

Staff Reporter of The Wall Street Journal

Millions of boxes of General Mills Inc. breakfast cereal containing traces of an unauthorized pesticide were sold in the U.S. for more than a year before the chemical's presence was discovered, the government disclosed yesterday.

Government officials don't believe the chemical, chlorpyrifos-ethyl, presents a health hazard, but its undetected presence in an important segment of the nation's food supply for so long has regulators wondering what went wrong.

Food and Drug Administration officials said the pesticide misuse dates back at least to May 1993. It was discovered last month in a routine test by FDA inspectors. During the 13 months of misuse, at least 11 General Mills cereals—including its best-selling Cheerios brands—were made with oats sprayed with it in storage with chlorpyrifos-ethyl, according to authorities at the Environmental Protection Agency, which is investigating the matter with the FDA.

The EPA identified the other cereals as Honey Nut Cheerios, Apple Cinnamon Cheerios, MultiGrain Cheerios, Lucky Charms, Kit, Fruiteberry, three varieties of Quaker Oats cereals and Feste's Peanut Butter Puffs, one of the company's newest products.

FOOD

"There's no question that the public has been eating adulterated cereals for at least a year," said Robert Lutz, director of the Office of Policy and Planning in the FDA's food safety division.

The pesticide apparently was knowingly mislabeled by an independent contractor that billed General Mills, the nation's second largest cereal maker, for a more expensive spray it should have been using to treat oats, authorities said.

The contractor, Pambion Inc., Edina, Minn., has since been dissolved by the company, and Minnesota authorities said they are looking into whether the company's chemical applicator license should be revoked.

The FDA notified General Mills of its findings June 30. "We said, 'That can't be. We don't use that chemical,'" a company spokesman said. But after company executives and others worked over the next weekend, he said, "we found that they were right."

General Mills said its own toxicologists immediately undertook further tests to verify that the presence of chlorpyrifos-ethyl in its cereals posed no health risk to the public. "Basically, we felt there was only one question, we wouldn't have waited for the

month, the U.S. government hadn't been asked to approve the pesticide for use on oats.

The General Mills spokesman emphasized that while some tainted oats had been unwittingly manufactured into cereal, perhaps two-thirds of the known supply remains under its control in a government-mandated quarantine. Chlorpyrifos-ethyl, the approved oats pesticide, is applied to grain intended to be stored three months or more, but many of the oats that went into the company's cereals came from fresh, clean supplies, the spokesman said.

Indeed, General Mills is sitting on 15 million bushels of oats sprayed with the unauthorized pesticide, unable to move them pending a determination as to their future. At cereal cash-grain prices, those oats would cost nearly \$20 million to replace. The company has also quarantined about 50 million boxes of cereal.

While the company said it isn't certain yet how it might dispose of the unlimited grain, it has told authorities it won't process the oats into food for human consumption. A possible alternative would be to sell them as animal feed, perhaps to horses.

The FDA authorities said yesterday that some of the suspect grain was sold by these firms to Page 27. Orlowski 1



Cereals that contained pesticide

federal government" to act, the spokesman said. "We would have pulled the product immediately."

Chemically, chlorpyrifos-ethyl and chlorpyrifos-ethyl are siblings, said a spokesman for their manufacturer, Dow Chemical, a joint venture of Dow Chemical Co. and Lilly & Co. The ethyl version is "used on a variety of growing crops, but not stored crops," he said. It isn't approved for use on oats in the U.S., but it can be used on growing corn and wheat, as well as soybeans and alfalfa. In Canada, he said, it is approved for use on growing oats but not on stored oats. "I said last

General Mills Breakfast Cereals With Pesticide Were Sold for Year

Continued From Page B1

General Mills to other companies — their identities couldn't be determined — that were being notified of the problem.

Meanwhile, federal and state authorities are looking into the activities of Y. George Roggy, who they said operates Fumicon from his suburban Minneapolis home. "We are investigating whether we should be revoking or suspending his license," said Minnesota Assistant Agriculture Commissioner Bill Oemichen. Repeated attempts to contact Mr. Roggy yesterday were unsuccessful.

An affidavit filed by an FDA special agent seeking a search warrant quoted General Mills officials who said Mr. Roggy told them on June 12 that he had knowingly substituted a pesticide "not approved by the FDA for use on oats. This substituted pesticide is Dursban. Mr. Roggy has admitted that he knew that Dursban was not approved for use on oats, but that he chose to use it because it was cheaper than Reidan 4E," the affidavit says. Dursban is the commercial name for chlorpyrifos-ethyl.

The U.S. attorney's office in Minneapolis said it executed search warrants on Mr. Roggy's home and on a semi-tractor-trailer used to store pesticides. The office noted that Mr. Roggy hadn't been charged either by complaint or indictment.

Initially, General Mills filed a request with the EPA for an expedited waiver of the prohibition on chlorpyrifos-ethyl on oats. That request, if approved, would allow the company to sell the six million cases of cereal containing the pesticide that are now warehoused. But one day after that request, the company asked the EPA to hold up any action while it considered its options. Asked yesterday what

those might include, the company spokesman declined to elaborate.

"We are pursuing all avenues for a timely resolution of the regulatory problem," he said. "We don't know yet whether the solution will come from the EPA, the FDA or both. . . . Everything we're doing is with the objective of getting the quickest possible resolution of this matter."

Should General Mills seek to export the cereal to a country with no restriction on chlorpyrifos-ethyl — and there is no indication that it will do so — both the EPA and the FDA said they would want to notify the importing country of the situation.

Last week, in announcing fiscal 1984 earnings, General Mills said it would probably have to restate those figures after it determines the significance of any charge the cereal episode might cost.

While it awaits word from the company, the EPA is planning to undertake what one official termed "a risk assessment, including evaluating toxicity and exposure information, and the potential dietary risk to the general U.S. population" to determine whether releasing the cereal for sale outweighs any potential health risks.

FDA officials said they are concerned that, should the government grant a waiver in this case and allow the cereal to be sold, it might send the wrong signal to other food manufacturers here and abroad. "That's not something we want to send," said the FDA's Mr. Lake.

"Companies that manufacture food products are obligated to make sure that their finished products are in compliance with those laws enacted to protect the public," he said. "Apparently this went on for 13 months and the company did not know it. . . . That's very disturbing. This could have been a more serious pesticide."



News/Information

Corporate Communications
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FOR IMMEDIATE RELEASE
July 7, 1994

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GENERAL MILLS RESUMES FULL PRODUCTION OF OAT CEREALS; ANNOUNCES CHARGE TO FISCAL 1994 EARNINGS

MINNEAPOLIS, MN-- General Mills announced today that it will not ship the oat-containing packaged foods products which it has had on voluntary hold since mid-June. The company also stated that it has resumed full production of these products from newly secured raw materials in full compliance with FDA and EPA regulations.

All costs associated with this decision will be reflected in the results of fiscal 1994. At present, General Mills estimates these costs could range from 40 cents per share to 55 cents per share. The company has reported preliminary earnings for fiscal 1994 of \$3.30 per share before any charge for unusual items. In fiscal 1993 General Mills earned \$3.10 per share including unusual items.

The company had voluntarily suspended production and shipments of some oat-containing products in mid-June when it learned that an independent licensed contractor had improperly treated some of the company's raw oat supplies with chlorpyrifos-ethyl as a substitute for the chemically similar chlorpyrifos-methyl, which is registered by the EPA for use on oats. Chlorpyrifos-ethyl is registered for use on wheat, corn, many fruits, vegetables, and animal feeds, but is not registered for use on oats. The contractor deliberately concealed the substitution from the company.

The FDA and EPA have stated that the products made from the improperly-treated oats pose no health hazard. However, the substitution resulted in a regulatory violation because chlorpyrifos-ethyl had not been registered with the EPA for use on oats.

The company has been working with the FDA and EPA to resolve the issue of the held stocks of finished product and raw oats. Establishment of a time-limited tolerance necessary to bring finished product into regulatory compliance now appears to be at least a six-week process. The company agrees that the process is appropriate, and stated that the EPA and FDA have been as cooperative as possible.

- MORE

Page-It Fax No. 7871	Date 7/7/94
To Jim O'Hara	From
On Behalf of FDA	C General Mills
Phone 1	Phone 1
Phone 2	Phone 2

-2-

However, much of the product in question would be past the "ship by" dates mandated by the company's strict quality standards for freshness by the end of the six-week process. Therefore, the company has decided to discontinue efforts to release held stocks, and none of the affected finished oat-products inventory produced before mid-June will be shipped. In announcing its decision the company said it had determined that the FDA would not permit shipment of the held product without EPA action on a time-limited tolerance. Work continues on an application to the EPA on an interim tolerance for raw oats for animal feed where time is not such a critical factor.

The company estimated that most stores would have adequate supplies of product in the week of July 11th as customer service approaches normal levels. Out of stock conditions estimated at about 30% were experienced in some stores during the last week in June and the first week in July. As service was interrupted until production was reinstated, June shipments were below target.

#*#

United States
Environmental Protection
Agency

Communications, Education,
And Public Affairs
(1703)



Note to Correspondents

FOR RELEASE: THURSDAY, JULY 28, 1994

A 13-count criminal indictment against a pesticide applicator has been returned by a federal grand jury in Minneapolis, Minnesota.

The attached press release details the indictment which resulted from an investigation conducted by EPA's Criminal Investigation Division and special agents from the U.S. Food and Drug Administration and the U.S. Department of Agriculture.

For further information, contact Wendy Butler at 202-260-4376.

R-189

John Kasper, Director
Press Services Division

OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

of pages **9**

Marion Fehrmback
DEVELOPER

Wendy
PHONE #

Fax # *202-260-4376*

Fax #

United States Attorney
District of Minnesota

NEWS RELEASE

Contact: Karen A. Jambor, Media Coordinator (612) 348-1514
David L. Lillehaug, United States Attorney (612) 348-1500

FOR IMMEDIATE RELEASE
Thursday, July 28, 1994

MINNEAPOLIS, MINNESOTA - United States Attorney David L. Lillehaug today announced that an Edina businessman was charged by a federal grand jury with knowingly spraying an unapproved pesticide on almost 17 million bushels of oats used by General Mills in the production of approximately 160 million boxes of some of the nation's best known breakfast cereals, including Cheerios and Lucky Charms.

Y. George Roggy, 45, of Edina, was indicted on eleven counts of mail fraud, one count of adulterating food and one count of misusing pesticides. The indictment, returned July 27 by a federal grand jury in Minneapolis, was sealed pending Roggy's arrest.

For over a year, Roggy's Edina-based company, Fumicon, was under contract with General Mills to apply an approved pesticide called Reldan on oats stored by General Mills at grain elevators in the port of Duluth/Superior. The grand jury charged that Roggy knowingly substituted Dursban, a pesticide not approved for stored oats, for Reldan. The indictment alleges that Roggy substituted Dursban because it was more than 50% cheaper than Reldan.

According to the indictment, Roggy submitted invoices totaling \$166,120 to General Mills that falsely represented that he had used the approved pesticide Reldan. He allegedly saved \$85,319 by his conduct.

(MORE)

News Release - Roggy - Page 2

U.S. Attorney David L. Lillehaug commented, "The federal regulatory agencies have informed us that, luckily, the pesticide substitution did not create a human health hazard. Regardless, this indictment essentially alleges that one man, to line his own pockets, took it upon himself to decide that millions of adults and children should unknowingly ingest an unapproved pesticide as they ate their breakfast Cheerios. According to the grand jury, that decision was not his to make and constituted criminal conduct."

Special agents of the U.S. Department of Agriculture, U.S. Environmental Protection Agency and the U.S. Food and Drug Administration, Office of Criminal Investigations executed three search warrants on June 16, one on Roggy's Edina home and two on semi-tractor trailers used to store pesticides. During the search, federal agents seized documents and other records regarding the purchase, use and application of Dursban by Roggy.

If convicted, Roggy faces a maximum potential penalty of five years in prison and/or a \$250,000 fine on each of the eleven counts of mail fraud, up to three years in prison and/or a \$250,000 fine for the adulteration of food charge and up to thirty days in prison and/or a \$5,000 fine for the misuse of a pesticide charge.

The case is the result of a joint investigation by the U.S. Food and Drug Administration, Office of Criminal Investigations, the U.S. Environmental Protection Agency, Criminal Investigation and the U.S. Department of Agriculture, Office of Inspector General. Assistant United States Attorney Richard G. Morgan and FDA Associate Chief Counsel for Enforcement Nancy F. Spodick are prosecuting the case.

* * * *

Criminal indictments are only charges and not evidence of guilt. A defendant is presumed to be innocent unless and until proven guilty.

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA,

Plaintiff,

v.

Y. GEORGE ROGGY,

Defendant.

INDICTMENT

(18 U.S.C. § 1341)

(21 U.S.C. § 331(k))

(7 U.S.C. § 136j)

THE UNITED STATES GRAND JURY CHARGES THAT:

COUNTS I - XI

(MAIL FRAUD, 18 U.S.C. § 1341)

1. At all times material and relevant to this

Indictment:

-- a. Defendant Y. GEORGE ROGGY owned and controlled Fumicon, Inc. (hereinafter "Fumicon"), a Minnesota Corporation, primarily doing business at 5216 West 70th Street, Edina, Minnesota, and engaged in the business of applying pesticide chemicals, among other activities. Defendant Y. GEORGE ROGGY was responsible for the day-to-day operations of Fumicon.

b. General Mills, Inc. (hereinafter "General Mills") was a Delaware corporation, doing business in the State and District of Minnesota and elsewhere, and engaged in the production of consumer food products for distribution and sale, including breakfast cereals made in whole, or in part, from oats.

2. From a date unknown to the Grand Jury until at least on or about June 11, 1994, in the State and District of Minnesota and elsewhere, the defendant,

Y. GEORGE ROGGY.

did devise a scheme and artifice to defraud and to obtain money by means of false and fraudulent pretenses, representations, and promises, that induced General Mills to make payments to defendant, doing business as Fumicon, in a total amount of approximately \$166,000.00, defendant well knowing during this time that the pretenses, representations, and promises would be and were false when made. This scheme and artifice was, in substance, as follows:

3. It was part of the scheme and artifice that defendant would and did agree with General Mills to apply the pesticide chemical chlorpyrifos-methyl, commonly sold under the trade name Reldan 4E (hereinafter "Reldan"), to oats unloaded from ships into grain storage elevators and mills located, among other places, in Duluth, Minnesota and Superior, Wisconsin. Reldan was authorized for use on food, including oats in storage, if properly applied.

4. It was further part of the scheme and artifice that defendant would and did purchase to apply to said oats a different pesticide chemical, chlorpyrifos-ethyl, commonly sold under the trade name Dursban 4E (hereinafter "Dursban").

5. It was further part of the scheme and artifice that defendant would and did apply Dursban directly to said oats instead of Reldan. Defendant applied Dursban to approximately 16,836,592 bushels of oats, some of which oats General Mills used to make approximately 160 million boxes of breakfast cereals such

as Cheerios, Apple Cinnamon Cheerios, Lucky Charms, Honey Nut Cheerios and Multi Grain Cheerios.

6. It was further part of the scheme and artifice that defendant well knew that Dursban was not authorized for use on food, including grains in storage such as oats. Nevertheless, defendant purchased and applied Dursban because it was considerably less expensive than Reldan.

7. It was further part of the scheme and artifice that defendant would and did periodically submit invoices to General Mills which falsely represented that the defendant, doing business as Fumicon, had applied or caused to have applied Reldan to said oats, when defendant, in fact, knew that Reldan had not been applied to said oats.

8. It was further part of the scheme and artifice that defendant would and did periodically submit invoices to General Mills which falsely charged General Mills for the cost of, and the cost of the application of, Reldan, when defendant, in fact, knew that Reldan had not been used, and had not been applied to, said oats.

9. It was further part of the scheme and artifice that defendant would and did periodically receive checks from General Mills by means of the United States mail, as payments remitted to defendant by General Mills.

10. As a result of said scheme and artifice to defraud, defendant caused General Mills to pay him approximately \$149,116.16 for Reldan that he falsely represented he had been

and applied, instead of approximately \$65,797.12 for the Durban defendant had actually used and applied. Defendant's conduct resulted in a gain to defendant of approximately \$85,319.04.

11. On or about the dates listed below, in the State and District of Minnesota, the defendant,

Y. GEORGE ROGGE,

for the purpose of executing the aforesaid scheme and artifice to defraud and to obtain money by means of false and fraudulent pretenses, representations, and promises, and attempting to do so, did knowingly cause to be delivered by mail according to the directions thereon, as to each Count listed below, mailings from General Mills to himself, containing checks, as generally described and in the approximate amounts listed below:

<u>Count</u>	<u>Date</u>	<u>Check No.</u>	<u>Amount</u>
I	May 12, 1993	23830	13,111.51
II	May 20, 1993	23884	2,411.23
III	June 8, 1993	24007	1,718.81
IV	August 2, 1993	24353	12,650.22
V	October 13, 1993	25132	7,113.62
VI	October 29, 1993	25280	13,258.06
VII	November 17, 1993	25417	19,111.62
VIII	December 8, 1993	25609	41,671.58
IX	January 14, 1994	25863	9,714.23
X	February 10, 1994	26126	12,208.38
XI	June 1, 1994	27129	<u>\$31,149.09</u>

Total Amount \$166,120.15

all in violation of Title 18, United States Code, Section 1341.

COUNT VII

[ADULTERATION, 21 U.S.C. § 331(k) and 333(a)(2)]

1. The United States Grand Jury realleges and incorporates by reference paragraphs 1 through 10, inclusive, of Count I of this indictment as if fully set forth herein.

2. At all times material and relevant to this Indictment:

a. The Federal Food, Drug, and Cosmetic Act (hereinafter "FD & C Act") provided, among other things, that raw agricultural commodities could not contain illegal residues of pesticide chemicals.

b. Under the FD & C Act, Title 21, United States Code, Section 342(a)(2)(B), food was adulterated if it was a raw agricultural commodity and it bore and contained a pesticide chemical which was unsafe within the meaning of Title 21, United States Code, Section 346a.

c. Oats were a "food" within the meaning of Title 21, United States Code, Section 321(f) and a "raw agricultural commodity" within the meaning of Title 21, United States Code, Section 321(r).

d. Dursban was a "pesticide chemical" within the meaning of Title 21, United States Code, Section 321(q).

e. Dursban, as applied to oats in storage, was unsafe within the meaning of Title 21, United States Code, Section 346a.

3. On or about June 30, 1993, in the State and District of Minnesota, the defendant,

Y. GEORGE ROGGY,

did, with the intent to defraud and mislead, cause a quantity of oats, that were being held for sale after shipment in interstate commerce, to be adulterated within the meaning of Title 21, United States Code, Section 342(a)(2)(B), by administering a pesticide chemical, Dursban, which was unsafe as applied within the meaning of Title 21, United States Code, Section 346a, all in violation of Title 21, United States Code, Section 331(k) and 333(a)(2).

COUNT XIII

[MISUSE OF PESTICIDE, 7 U.S.C. § 136j(a)(2)(G)]

1. The United States Grand Jury realleges and incorporates by reference paragraphs 1 through 10, inclusive, of Count I of this Indictment as if fully set forth herein.

2. At all times material and relevant to this Indictment:

a. The Federal Insecticide, Fungicide and Rodenticide Act (hereinafter "FIFRA") was a federal statute setting forth criminal penalties for the use of pesticides in a manner inconsistent with their required labels.

b. Dursban was a registered pesticide as defined under FIFRA, and had an active ingredient known as chlorpyrifos-ethyl. Dursban was not registered with the United States Environmental Protection Agency for use on food, including grains in storage. The required pesticide label for Dursban forbade

application of Dursban on food or food-contacting surfaces within "food handling establishments" such as grain mills and storage elevators.

c. Defendant V. GEORGE ROGGY, doing business as Fumicon, used Dursban to treat oats that belonged to General Mills. The General Mills' oats to which the defendant applied Dursban were intended for use in General Mills' food products.

3. On or about June 30, 1993, in the State and District of Minnesota, the defendant,

V. GEORGE ROGGY,

did knowingly use the registered pesticide Dursban in a manner inconsistent with its labeling, in violation of Title 7, United States Code, Section 136j(a)(2)(G) and 1361(b)(2).

A TRUE BILL

UNITED STATES ATTORNEY

FOREPERSON

Dietary Risk Assessment for Chlorpyrifos on Oats

After FDA discovered residues of chlorpyrifos on oats stored by General Mills, a dietary risk assessment was requested to determine the human health risk for the unregistered pesticide on oats. A review of the dietary risk for chlorpyrifos on oats was requested because there was no published use for chlorpyrifos on oats as a potential grain protectant.

Due to the nature of the contamination the most appropriate analysis for estimation of dietary risk was the acute dietary assessment. The possibility that residues of chlorpyrifos on oats could be ingested over a short period of time prompted the need for an acute analysis. Previously only chronic analyses had been used to estimate the dietary risk from chlorpyrifos.

Toxicological Endpoint

The toxicological data for chlorpyrifos used in the chronic risk assessment had been accepted and verified by the Agency on September 9, 1993. There were no outstanding data gaps for registration of chlorpyrifos. A Reference Dose was assigned from a human 20 day feeding study. The toxicological effects seen in the human study used to calculate the Reference Dose showed decreased plasma cholinesterase as an endpoint effect. The No Observed Effect Level (NOEL) from the study was 0.03 mg/kg/day and an uncertainty factor of 10 was included to account for variability in humans. The Reference Dose to assess human dietary risk was therefore 0.003 mg/kg/day. This toxicological endpoint was used to estimate chronic dietary risk from chlorpyrifos on oats. Toxicology Branch I recommended that the same NOEL, 0.03 mg/kg/day, be used to calculate a Margin of Exposure (MOE) for acute dietary risk.

There was no evidence of carcinogenicity in studies submitted to the Agency and therefore a carcinogenic classification of E (no evidence) was assigned to chlorpyrifos. No estimation of human carcinogenic risk was evaluated for this chemical.

Residue Information

The residue database for chlorpyrifos in the Dietary Risk Evaluation System (DRES) was large and complex. Chlorpyrifos has a tolerance for food handling establishments (FHEs). In such cases there is the possibility for residues of chlorpyrifos to be in contact with all food passing through such establishments. In order to estimate the dietary risk for this type of use, the Agency generally puts the FHE tolerance in for every raw agricultural commodity unless there is a higher tolerance already established for a specific crop. This treatment of FHE tolerance is likely to vastly overestimate risk since it assumes that all food that a person eats has chlorpyrifos at least at the FHE level.

The single serving acute toxicity analysis for chlorpyrifos on oats considered the general public and especially infants and children for risk assessment. Consumption information used in the analysis was for consumers of oats only, not the entire age group. The analysis considered all oats, in all products in the USDA 1977-78 Nationwide Survey of Food Consumption (NFCS) database. DRES was not able to pull out consumption values for oat-containing-cereals only. This could be a source of overestimation of exposure to chlorpyrifos.

June 14, 1994 Analyses

The initial analyses for chlorpyrifos, both chronic and acute, used an exaggerated residue level of 6 ppm for oats. The Agency felt this was a very high residue for estimating

dietary risk; however, this residue would provide a "worst-case" estimate of risk. Both chronic and acute risk estimates were potentially of concern at this residue level.

The chronic dietary risk estimates for published tolerances (including FHE) plus oats at 6 ppm lead to an exposure equal to 51% of the RfD for the U.S. general population. The highest subgroup, non-nursing infants less than 1 year, had an exposure equal to 244% of the RfD. Due to inclusion of all FHE tolerances this estimate of chronic exposure was probably an overestimate of the chronic risk from chlorpyrifos on oats (see attached table on chronic exposure). Also, the chronic analysis assumes consumption of oats containing chlorpyrifos residues over a life time. Since this analysis did not characterize the risks from a short term exposure to chlorpyrifos on oats, the acute dietary analysis was deemed more appropriate.

The acute exposure analysis for chlorpyrifos on oats at the residue level of 6 ppm lead to risk estimates which were below the margin of exposure of 10. As noted above, the analysis only compared residues of oats for acute risk. Normal practice is to include all crops legally registered for use in the DRES analysis. In that sense, the acute analysis was not comparable to what is normally done for other chemicals. The Agency generally considers a margin of exposure above 10 to be safe when comparing to human toxicological studies, as in this case.

June 15, 1994 Analysis

The second analysis for chlorpyrifos for acute dietary risk was for a residue level of 0.3 ppm. Residues found by General Mills in finished oat cereal were all below 0.3 ppm (F. Hegele fax to USDA, 6/14/94). This lower residue level seemed more realistic for risk assessment and yet was still higher than the actual residues of chlorpyrifos being found on the oats by General Mills. Using the residue level of 0.3 ppm, the acute risk estimates were all above the margin of exposure of 10, again using the NOEL of 0.03 mg/kg/day from the human toxicological study as an endpoint. Considering the sources of overestimation and the safety factors built in to the risk estimates, the Agency felt the public was not at risk from acute exposure to chlorpyrifos by way of oats using the residue level of 0.3 ppm.

June 17, 1994 Analyses

Other acute assessments were conducted in order to estimate the residue level of chlorpyrifos which would be safe considering actual consumption values in the DRES database. It was estimated that for the 90th percentile consumer of oats, at residue levels of up to 0.6 ppm, a single serving a day of oats would be safe for infants and children and the general public.

Further Data

Recent Less than Lifetime Committee document on Chlorpyrifos (M. Van Gemert memo, 8/15/94) has recommended for a NOEL for acute dietary risk of 0.1 mg/kg/day instead of the more conservative 0.03 mg/kg/day used in the above mentioned analyses. Using this NOEL and residues up to 0.6 ppm, the margins of exposure for the acute analysis on oats alone are all above 10. Again, the Agency generally is not concerned if MOEs are above 10 when the NOEL is from a human study. The Agency will be reevaluating the existing uses of chlorpyrifos in reregistration scheduled for completion by March 1995.

JUN 17 1994

2:10 pm

Chronic exposure analysis
Chlorpyrifos on oats

	Non-nursing infants < 1 yr	General population
Current published tolerances (including oats at 0.005 ppm as anticipated residue from food handling establishment tolerance. FHE tolerance is 0.1 ppm.)	95%	34
plus oats at 0.2 ppm (--> cereal at 0.14 ppm)	99	35
plus oats at 0.3 ppm (--> cereal at 0.21 ppm)	102	35
plus oats at 0.6 ppm (--> cereal at 0.42 ppm)	104	36
plus oats at 1.0 ppm (--> cereal at 0.7 ppm)	120	37

Notes:

1. Assumes oats adds 2.5% of RfD for each 0.1 ppm residue for non-nursing infants < 1 year old, and 0.28% of RfD for the general population.
2. Includes food-handling establishment tolerance, but uses Anticipated Residue of 0.005 ppm for these commodities.
3. Pending tolerances on grapes, lettuce and tomatoes are not included. Effect is less than 0.5% of RfD for infants; 2.25% for general population.
4. Uses Anticipated Residues and percent-crop-treated for non-food-handling establishment commodities, where available. (None used for oats.)

Manis

Swordfish and shark taste great—especially grilled or broiled. But reports that these and some other large predatory fish may contain methyl mercury levels in excess of the Food and Drug Administration's 1 part per million (ppm) limit has dampened some fish lovers' appetites.

FDA scientists responsible for seafood safety are also concerned about the safety of eating these types of fish, but they agree that the fish are safe, provided they are eaten infrequently (no more than once a week) as part of a balanced diet.

Mercury occurs naturally in the environment. According to FDA toxicologist Mike Bolger, Ph.D., approximately 2,700

to 6,000 tons of mercury are released annually into the atmosphere naturally by degassing from the Earth's crust and oceans. Another 2,000 to 3,000 tons are released annually into the atmosphere by human activities, primarily from burning household and industrial wastes, and especially from fossil fuels such as coal.

Mercury vapor is easily transported in the atmosphere, deposited on land and water, and then, in part, released again to the atmosphere. Trace amounts of mercury are soluble in bodies of water, where bacteria can cause chemical changes that transform mercury to methyl mercury, a more toxic form.

Fish absorb methyl mercury from water as it passes over their gills and as they feed on aquatic organisms. Larger predator fish are exposed to higher levels of methyl mercury from their prey.

Methyl mercury binds tightly to the proteins in fish tissue, including muscle. Cooking does not appreciably reduce the methyl mercury content of the fish.

Nearly all fish contain trace amounts of methyl mercury, some more than others. In areas where there is industrial mercury pollution, the levels in the fish can be quite elevated. In general, however, methyl mercury levels for most fish range from less than 0.01 ppm to 0.5 ppm. It's only in a few species of fish that methyl mercury levels reach the FDA limit for human consumption of 1 ppm. This most frequently occurs in some large predator fish, such as shark and swordfish. Certain species of very large tuna, typically sold as fresh steaks or sushi, can have levels over 1 ppm. (Canned tuna, composed of smaller species of tuna such as skipjack and albacore, has much lower levels of methyl mercury, averaging only about 0.17 ppm.) The average concentration of methyl mercury for commercially important species (mostly marine in origin) is less than 0.3 ppm. (See the accompanying chart.)

FDA works with state regulators when commercial fish, caught and sold locally, are found to contain methyl mercury levels exceeding 1 ppm. The agency also checks imported fish at ports and refuses entry if

methyl mercury levels exceed the FDA limit.

Sport-caught predator fresh-water species like pike and walleye sometimes have methyl mercury levels in the 1 ppm range. Other fresh-water species also have elevated levels, particularly in areas where mercury levels in the local environment are elevated.

FDA suggests sports fishers check with state or local governments for advisories about water bodies or fish species. These advisories provide up-to-date public health information on local areas and warn of areas or species where mercury (or other contamination) is of concern.

Safety Studies

Eating commercially available fish should not be a problem, say FDA toxicologists. The 1-ppm limit FDA has set for commercial fish is considerably lower than levels of methyl mercury in fish that have caused illness.

For information about the likely outcome of eating fish with low levels of methyl mercury, scientists look to studies of persons exposed to high levels: in particular, studies of two poisoning episodes from highly contaminated fish in Japan in the 1960s, and another poisoning incident in Iraq in the 1970s involving contaminated grain.

In the first episode, which occurred in Minamata, Japan, 111 people died or became very ill (mostly from nervous system damage) from eating fish (often daily over extended periods) from waters that were severely polluted with mercury from local industrial discharge.

Following a similar incident in Nagata, Japan, where 120 persons were poisoned, studies showed that the harm caused by methyl mercury poisoning, particularly the neurological symptoms, can progress over a period of years after exposure has ended. The average mercury content of fish samples from both areas ranged from 9 to 24 ppm, though in Minamata, some fish were found to have levels as high as 40 ppm. Fortunately, no similar incidents have occurred in the United States.

The best indexes of exposure to methyl mercury are concentrations in hair and blood. The average concentration of total mercury in non-exposed people is about 8 parts per billion (ppb) in blood and 2 ppm in hair. From the Japanese studies, toxicologists learned that the lowest mercury level in adults associated with toxic effects

Sample Results

Results of FDA sampling for methyl mercury by species for October 1990 to October 1991 (the action level is 1 ppm).

Fish Species	Range (ppm)
Bass, fresh water	0.15-0.34
Catfish, fresh and salt water	< 0.10-0.31
Cod	Trace
Crabs	0.10-0.15
Croaker	0.13-0.32
Flounder	ND-0.08
Grouper	0.35-0.48
Haddock	Trace
Lobster	0.10-0.14
Mackerel	0.10-0.23
Mahi mahi (dolphin)	0.11-0.21
Marlin	0.10-0.92
Orange roughy	0.42-0.71
Oysters	< 0.10
Perch, fresh water	ND-0.31
Perch, ocean	
(rosefish, red rockfish)	Trace-0.03
Pike	Trace-0.16
Pollock	ND-0.10
Salmon	ND-0.11
Shrimp	< 0.10
Shark	0.23-2.95
Snapper, red	0.07-0.26
Swordfish	0.26-3.22
Trout	Trace-0.13
Tuna, canned	ND-0.75

ND means none detected

(paresthesia) was 200 ppb in blood and 50 ppm in hair, accumulated over months to years of eating contaminated food.

The Japanese studies did not, however, provide information on what levels of methyl mercury might adversely affect the fetus and infant.

"There is no doubt that when humans are exposed to high levels of methyl mercury, poisoning and problems in the nervous system can occur," Bolger says.

The types of symptoms reflect the degree of exposure. Paresthesia (numbness and tingling sensations around the lips, fingers and toes) usually is the first symptom. A stumbling gait and difficulty in articulating words is the next progressive symptom, along with a constriction of the visual fields, ultimately leading to tunnel vision and impaired hearing. Generalized muscle weakness, fatigue, headache, irritability, and inability to concentrate often occur. In severe cases, tremors or jerks are present. These neurological problems frequently lead to coma and death.

"During prenatal life, humans are susceptible to the toxic effects of high methyl mercury exposure levels because of the sensitivity of the developing nervous system," Bolger explains. Methyl mercury easily crosses the placenta, and the mercury concentration rises to 30 percent higher in fetal red blood cells than in those of the mother.

"But none of the studies of methyl mercury poisoning victims have clearly shown the level at which newborns can tolerate exposure," Bolger says. "It is clear that at exposure levels that affect the fetus, adults are also susceptible to adverse effects.

What is not clear is the effect, if any, on fetuses at much lower levels—those that approach current exposure levels through normal fish consumption."

Studies of the poisoning incident in Iraq have provided limited data about what effects low levels of methyl mercury exposures to the fetus have on the infant. One possible effect, for example, is lateness in walking. In the fall and winter of 1971-72, wheat seed intended for planting—and which had therefore been treated with an



alkyl mercury fungicide—was mistakenly used to prepare bread; more than 6,500 Iraqis were hospitalized with neurological symptoms and 459 died. The vast majority of the mothers experienced exposures that resulted in hair levels greater than the lowest levels associated with effects in adults. But there was no clear evidence that the fetus was more sensitive than the adult to methyl mercury.

Another study on methyl mercury toxicity was published by the World Health Organization in 1990. It concluded, "the

general population does not face a significant health risk from methyl mercury."

Bolger says there is a consensus among scientists on all the results of this study except for the findings related to the relationship between low exposure levels and fetal toxicity.

Searching for More Information

FDA and the National Institute of Environmental Health Sciences are supporting a study by the University of Rochester to gather conclusive data on the effects of

FDA Advice for Consumers

Fish is an important source of high-quality protein, vitamins and minerals. FDA seafood specialists say that eating a variety of types of fish, the normal pattern of consumption, does not put anyone in danger of mercury poisoning. It is when people eat fad diets—frequently eating only one type of food or a particular species of fish—that they put themselves at risk.

Pregnant women and women of childbearing age who may become pregnant, however, are advised by FDA experts to limit their consumption of shark and swordfish to no more than once a month. These fish have much higher levels of methyl mercury than other commonly consumed fish (see accompanying chart). Since the fetus may be more susceptible than the mother to the adverse effects of methyl mercury, FDA experts say that it is prudent to minimize the consumption of fish that have higher levels of methyl mercury, like shark and swordfish. This advice covers both pregnant women and women of childbearing age who might become pregnant, since the first trimester of pregnancy appears to be the critical period of exposure for the fetus. Dietary practices immediately before pregnancy would have a direct bearing on fetal exposure during the first trimester, the period of greatest concern.

FDA toxicologists have determined that for persons other than pregnant women

and women of childbearing age who may become pregnant, regular consumption of fish species with methyl mercury levels around 1 part per million (ppm)—such as shark and swordfish—should be limited to about 7 ounces per week (about one serving) to stay below the acceptable daily intake for methyl mercury. For fish with levels averaging 0.5 ppm, regular consumption should be limited to about 14 ounces per week. Current evidence indicates that nursing women who follow this advice do not expose their infants to increased risk from methyl mercury.

Consumption advice is unnecessary for the top 10 seafood species, making up about 80 percent of the seafood market—canned tuna, shrimp, pollock, salmon, cod, catfish, clams, flatfish, crabs, and scallops. This is because the methyl mercury levels in these species are all less than 0.2 ppm and few people eat more than the suggested weekly limit of fish (2.2 pounds) for this level of methyl mercury contamination.

FDA's action level of 1 ppm for methyl mercury in fish was established to limit consumers' methyl mercury exposure to levels 10 times lower than the lowest levels associated with adverse effects (paresthesia) observed in the poisoning incidents. FDA based its action level on the lowest level at which adverse effects were found to occur in adults. This is because that level of exposure was actually lower

than the lowest level found to affect fetuses, affording them greater protection.

FDA toxicologists are developing a more complete database for addressing low-level methyl mercury exposures from fish; however, they consider the 1-ppm limit to provide an adequate margin of safety. This doesn't mean that it is safe to regularly and frequently eat fish that contain 1 ppm methyl mercury. The limit was established taking into consideration the types of fish people eat, the levels of methyl mercury present in each species, and the amounts of fish that are normally consumed.

Not everyone agrees, however, about what advice to provide to consumers. This is particularly evident in sport fish advisories provided by states around the country. Because states often use different criteria for their fish advisories, adjoining states may provide different advice about fish from the same bodies of water. Some states have adopted a zero risk approach and have advised consumers not to eat certain species, while others have advocated a limit on intake that is more consistent with the FDA approach.

Despite these differences, efforts by the states remain a valuable guide for alerting people to possible mercury contamination in certain fish species in particular bodies of water. Federal efforts are being made to increase uniformity in fishing advisories. ■

Questions?

FDA invites consumers who have questions about methyl mercury in fish or other seafood concerns to telephone the 24-hour FDA Seafood Hotline at (1-800) FDA-4010 or (202) 205-4314 (in the Washington, D.C., area). The automated hot line and Flash Fax service are available 24 hours a day. Public affairs specialists can be reached at the same numbers from noon to 4 p.m. Eastern time, Monday through Friday. ■

long-term exposure to low levels of methyl mercury in the fetus and infant. The study is being conducted in the Seychelles Islands, off the coast of East Africa in the Indian Ocean.

Fish is the major source of protein for people in the Seychelles Islands. Begun about 10 years ago, the study focuses on the approximately 700 pregnancies that occur on the islands each year.

"That's a much more significant database than we had in the Iraqi study," says Bolger. "Also, the population is mostly Muslim," he says, a religion that prohibits smoking and drinking, behaviors that could affect the prenatal health of fetuses

(and interfere with efforts to understand the subtle effects of methyl mercury).

The study tracks women from pregnancy to childbirth, and monitors the babies' consumption of breast milk. As children grow older, they are followed for any signs of nervous system disorders. Reports from the Seychelles study are not ready for publication, but Bolger expects the results to make a significant contribution to the consideration of whether further regulatory controls or other actions may be needed. ■

Judith E. Foulke is a member of FDA's public affairs staff.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 01 1994

Food and Drug Administration
Rockville MD 20857

The Honorable Edolphus Towns
Chairman, Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
B-372 Rayburn House Office Building
Washington, D.C. 20515-3210

Dear Mr. Chairman:

The purpose of this letter is to transmit to you the edited transcripts of Dr. Fred Shank and Dr. Stephen Sundlof from the hearing on Chemical Residues in Food that took place on September 28, 1994, before your Subcommittee.

In addition, enclosed are

- a response to the question raised at the hearing [transcript, p. 101], regarding the number of tests performed on milk by FDA, the states, and the industry; and
- materials for the record that FDA promised to submit in the written statement:
 - 1) a summary report on the Total Diet Study which describes the findings of this program in greater detail (written statement, p. 5);
 - 2) the 1993 summary of FDA's pesticide residue monitoring program; (written statement, p. 22);
 - 3) a chronology of FDA's lead reduction activities (written statement, p. 27); and
 - 4) a list of regulatory limits for lead in various products under FDA jurisdiction (written statement, p. 27).

Page 2 - The Honorable Edolphus Towns

We will forward repsonses to the questions submitted from you and Representative Sanders shortly.

If you have any questions, please contact Carolyn Hommel on my staff, at 301/443-3793.

Sincerely,

Terry Stullard for
Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosures

FDA Total Diet Study, July 1986--April 1991,

Dietary Intakes of Pesticides, Selected Elements, and Other Chemicals

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ABSTRACT

The U.S. Food and Drug Administration conducts the Total Diet Study to determine dietary intakes of selected pesticides, industrial chemicals, and elements (including radionuclides). The reported results reflect the sampling period from July 1986 to April 1991. The study involves retail purchase of foods representative of the "total diet" of the U.S. population, preparation for "table-ready" consumption, and individual analyses of 234 items depicting the diets of 8 population groups. The diets were based on 2 nationwide food consumption surveys. The data presented represent 21 food collections (also termed "market baskets") in regional metropolitan areas during the 5-year period. Dietary intakes of nearly 120 analytes are presented for the 8 population groups, which range from infants to elderly adults. Intakes of selected population groups are compared with representative findings from earlier Total Diet Study sampling periods. As reported previously, average daily intakes are well below acceptable limits.

The U.S. Food and Drug Administration (FDA) instituted a revised Total Diet Study in April 1982. At that time, major changes were incorporated into this program, which has been conducted by FDA since 1961. This paper discusses 1986-1991 results; findings for the 1982-1984 and 1984-1986 periods have been reported previously (1, 2). Pesticide findings for the years 1987-1991 have also been reported (3-8).

Purposes of Study

The Total Diet Study, also known as the Market Basket Study, has been an important part of FDA's monitoring program for chemical contaminants in the U.S. food supply for many years. The primary purposes of this study are to: (1) estimate the dietary intakes of pesticides, industrial chemicals, toxic elements, radionuclides, and essential minerals, and (2) compare these intakes with established dietary intake levels. Depending on the chemical substance being evaluated, these "established" intakes include Acceptable Daily Intakes (ADIs), Provisional Tolerable Weekly Intakes, (PTWIs), Recommended Dietary Allowances, or Estimated Safe and Adequate Daily Dietary Intakes. The study also allows FDA to identify trends, follow up on isolated contamination incidents, and check the effectiveness of U.S. regulations and initiatives relative to levels of chemicals in foods. Additionally, the results serve to guide FDA's other monitoring programs.

Evolution of Study

The current study is the product of continual evolution and refinement since its inception in 1961. The study's initial objective was to determine the dietary intake of radionuclides resulting from atmospheric testing of nuclear weapons. However, because of the availability of representative samples, analyses for selected nutrients and pesticides were also included (9).

The original diet, which reflected quantities consumed by 16- to 19-year-old males, was modified to meet nutritional goals and consisted of 82 foods divided into 11 food groups (9). This diet was developed using the U.S. Department of Agriculture's (USDA's) 1955 Household Food Consumption Survey and the USDA's "Food Plan at Moderate Cost" (9). The diet was tailored to theoretically meet recommended

nutritional allowances while providing for assessment of maximum chemical contaminant intake, both with regard to daily weight of food as consumed and food types (milk, vegetables, grain) likely to contain the contaminants sought at the time. Originally, the foods were purchased 4 times a year at the retail level in Washington, DC, prepared for consumption, and analyzed. Later, the foods were purchased in different regions of the country. Early in the program, the foods were divided into composite food groups (e.g., dairy products, leafy vegetables, etc.), the foods in each group were blended in amounts proportional to the weights consumed, and the composite foods were analyzed by the FDA laboratory in the district that collected the samples (9). Subsequently, adjustments were made to reflect regional food consumption differences (9), the annual number of market basket collections was increased to about 30, and analyses for certain toxic elements and industrial chemicals were added.

A revised adult diet was adopted in 1971 (9) and continued until April 1982. It was based on the USDA's 1965 Household Food Consumption Survey and the 1964 moderate cost food plan for 15- to 20-year-old males (9). Individual diets representing the western, central, southern, and eastern areas of the U.S. were developed with appropriate regional variations in the foods and their consumption rates. Approximately 120 foods were represented in 12 composite food groups; generally 20-30 "market basket" samples of these foods were collected each year. Also, beginning with fiscal year 1971, all analytical work (except for radionuclides) was conducted by the FDA Kansas City District laboratory (9).

Beginning with fiscal year 1975, separate infant (6-month-old) and toddler (2-year-old) studies were added to the program. These diets were developed on a regional basis as described previously. They contained approximately 50 and 110 foods, respectively, and each was represented by 11 composite food groups (9).

The Total Diet Study conducted before April 1982 utilized what may be termed a "composite sample approach" regardless of the diet (adult, infant, or toddler) or the total number of foods involved. Foods representative of a particular diet were purchased at the retail level, prepared as for consumption in a manner similar to that used in the home (washed, trimmed, boiled, baked, etc.), and divided into similar

groups (e.g., dairy products, leafy vegetables, etc.). The individually prepared group members were then composited by weight in amounts representative of food consumption figures determined from the USDA dietary survey information. The analyses for chemical contaminants, while originally restricted to less than 2 dozen pesticides and radionuclides, were expanded over the years to include a wide array of pesticides, their alteration products, industrial chemicals, and toxic elements. Analyses for certain minerals were also incorporated. Reports cited elsewhere summarize the findings of pesticides, industrial chemicals, and toxic elements in adult, infant, and toddler diets analyzed using the composite approach (9).

Revised Study

The most significant revision of the Total Diet Study was implemented in April 1982. This redesigned study, based on updated dietary survey information and analysis of individual foods, allows for assessing dietary intakes of a greater number of age-sex groups. The dietary revision was based on 2 nationwide surveys: the USDA's 1977-78 Nationwide Food Consumption Survey and the 1976-1980 National Center for Health Statistics' Second National Health and Nutrition Examination Survey (9). These surveys covered approximately 50 000 participants; over 5000 foods were identified. By use of an aggregation scheme (10, 11), 234 foods were selected to represent all 5000 foods. (Thirty-three of the 234 foods are commercially prepared infant or junior foods.) Each of the 234 food items represents a group of foods similar in type and nutrient content; the analyzed item is that group member consumed in the greatest amount. Apple pie, for example, represents all types of apple pies (homemade, bakery-purchased, frozen, apple with raisin, etc.) and all other fruit pies and pastry with fruit.

Use of this approach allows the "total diet" (i.e., 100%) of the U.S. population to be represented by a relatively small number of food items. Without aggregation, approximately 500 and 900 foods would be required to account for 90 and 95% by weight of the average diet, respectively (10).

The individual foods and necessary recipe ingredient items are purchased by FDA personnel in retail markets in each of 4 broad geographic areas each year. The sampling dates and collection areas covered

during this 5-year reporting period are shown in Table 1. FDA field personnel follow a shopping list detailing the items to be purchased. The foods may be categorized as follows: individually analyzed items; items analyzed individually, but which are also ingredients in other items (e.g., milk); items which are used only as recipe ingredients and are not analyzed individually. Detailed listings of these food items have been published (11).

The food items for each market basket are collected simultaneously in 3 cities of 1 of the 4 geographic areas over a 4-week period and are shipped to the Total Diet Laboratory in Kansas City, MO (current location, Lenexa, KS). Seasonal items are collected in the appropriate city when they become available. After preparation according to specific instructions (11), the 3 like food items collected in different locations are combined, yielding the 234 cooked or otherwise table-ready food items to be analyzed. The degree of preparation varies from that easily done in the laboratory (e.g., peeling bananas) to the more complex preparation of recipe items (e.g., homemade beef and vegetable stew). The majority of the food preparation and all of the cooking is performed by a kitchen under contract to FDA.

The individual items in each market basket sample are then analyzed for residues of nearly 200 pesticides plus many industrial chemical contaminants, such as polychlorinated biphenyls (PCBs), and "toxic" elements and essential minerals (mercury, lead, cadmium, arsenic, selenium, zinc, copper, iron, magnesium, manganese, potassium, phosphorus, calcium, sodium, and iodine). Most of the analyses employ multiresidue analytical methods; 5 different methods are used for pesticides. These analytical methods and the analytes determined are cited elsewhere (9). Analyses of the individual items of 1 market basket sample are conducted annually for the radionuclides strontium-90, cesium-137, iodine-131, and ruthenium-106 at the FDA Engineering and Analytical Center, Winchester, MA; the most recent findings have been discussed by Cunningham *et al.* (12). Only Total Diet Study results for pesticides, industrial chemicals, and selected elements are reported in this paper.

Total Diet Study analyses are performed on foods prepared for consumption rather than on raw, unwashed commodities, as is the case in most FDA monitoring for enforcement of tolerances or other

regulatory limits. Therefore, because food preparation may reduce levels of pesticide or other chemical residues, the analytical procedures used in the Total Diet Study are modified to permit quantitation at levels 5-10 times lower than those used in FDA programs for enforcement of regulatory limits. (A greater equivalent sample weight is submitted to the final determinative step.) Identities of pesticide and other organic chemical residues are confirmed by alternative technique(s), such as thin-layer chromatography, mass spectrometry, element-selective detectors, etc. A continuing quality assurance program is carried out; it includes frequent analyses of "blank" samples and fortified control test samples. For all methods involving organic analyses, a minimum of 1 reagent blank is determined per 20 analyses; recovery determinations are conducted at the rate of 1 in 7-10 analyses, depending on methodology. Similar requirements apply to elemental analyses.

The dietary intakes of the various analytes are then calculated for the 8 population groups from the levels found in each of the foods.

Findings

The sampling dates and collection areas for the 21 market baskets covered during the 5-year reporting period are listed in Table 1. Each of the 4 geographic areas previously mentioned is represented by 5-6 regional collections (15-18 individually collected market baskets) in the 5-year period.

Pesticides and Industrial Chemicals

Of the nearly 300 organic chemicals that can be determined by the analytical procedures used (9), an average of 63 different pesticides and industrial chemicals were found in each market basket of 234 foods. In the entire 5-year period, 113 different pesticide, pesticide-related, and industrial chemical residues were found; their dietary intakes are given in Table 2. The most frequently found organic chemical residues are listed in Table 3, together with the total number of findings and the percent incidence of occurrence based on the total of 4914 individual food samples analyzed.

Table 2 shows the mean daily intake/unit of body weight ($\mu\text{g}/\text{kg}$ of body weight/day) of the pesticides and industrial chemicals found. The mean body weights for the 8 population groups are 9 kg (6-11 months), 13 kg (2 years), 54 kg (14-16 year females), 60 kg (14-16 year males), 60 kg (25-30 year females), 76 kg (25-30 year males), 64 kg (60-65 year females), 76 kg (60-65 year males). These daily intakes per unit of body weight may be compared with ADIs established by scientific experts who attend annual joint meetings of the United Nations' Food and Agriculture Organization and the World Health Organization (FAO/WHO) to evaluate, among other things, the toxicity of pesticides. The ADI is the daily amount of a chemical which can, over an entire lifetime, be consumed without appreciable risk (13). Current ADIs (14) and the percentage of the ADI based on the daily intake of the 14-16 year male are listed in Table 2. Note that ADIs are not established for all chemicals and that some ADIs include several chemicals which may be related because of their formation during manufacturing or as a result of environmental degradation (e.g., endosulfan).

The daily intakes reported in Table 2 were calculated on the basis of concentration levels uncorrected for analytical recoveries, which generally equal or exceed 80%. Although the limit of quantitation varies with the chemical and food item, it is generally on the order of 0.001 ppm or less for compounds comprised of a single chemical entity. (Residues consisting of a mixture of related chemicals, e.g., toxaphene, generally have much higher limits of quantitation.) Chemicals whose identities were confirmed, but which were present at levels below the limit of quantitation, were considered to be "trace" values. In the calculation of organic chemical intakes, such trace findings were assigned values estimated by the laboratory. Results of analyses in which no residues were detected were equated to zero in the calculation of intakes.

Elements

The average daily intakes of 4 elements for the 8 population groups are presented in Table 4. The concentration levels used in calculating intakes were not corrected for analytical recoveries. Trace levels were assigned values as described above. Results of analyses in which no residues were detected were treated as above. Tolerable intake limits are also shown. For the toxic elements cadmium, lead, and

mercury, the Provisional Tolerable Daily Intakes (PTDI) are listed. The PTDIs were derived from the FAO/WHO PTWLs; these are maximum intakes reflecting dietary and other sources (e.g., air) that appear to be without appreciable risk (13, 15). In the case of lead, the FDA proposed Provisional Tolerable Total Intake Levels (PTTILs) and representative intakes (expressed in $\mu\text{g}/\text{day}$) are also briefly addressed below.

Total Diet analyses determine total arsenic, both organic and inorganic. No maximum tolerable intake has been set for organic arsenic, although the FAO/WHO has estimated a PTDI for ingested inorganic arsenic of about 2 $\mu\text{g}/\text{kg}$ body weight (16).

Findings of 11 nutritional elements determined via the Total Diet Study have been published (17).

Discussion

The daily dietary intakes for analytes historically showing relatively consistent findings or trends (e.g., total DDT, dieldrin, lead) may significantly differ from intakes determined prior to the 1982 redesign of the Total Diet Study. Such intake fluctuations may result from the different approaches used. Examples of changes in the Total Diet Study contributing to this effect include design of diets (items included and their weight representation); analysis of individual foods versus analysis of composites, which effectively reduces quantitation limits for determining residues present in the individual food; use of different or additional analytical methods which may have affected recovery values or increased capability of residue detection.

A comparison of daily intakes ($\mu\text{g}/\text{kg}$ body weight/day) for selected chemicals during the 1982-84, 1984-86 and 1986-91 periods is shown in Table 5. Particularly noteworthy is the reduction in lead intakes, which reflects in large part the then-diminishing use of lead solder in food cans. (By 1992, the use of lead solder in food cans in the U.S. had been virtually eliminated, resulting in further reduction of dietary lead intake.)

Table 6 shows the number of different organic residues related to pesticides and industrial chemicals

found in the entire 5-year period in individual food items exhibiting the greatest residue variety. The information in Table 6 illustrates certain product-related residue patterns. For example, in the 21 samples of dry roasted peanuts analyzed during this period, 18 different organic residues were detected, with a mean of 12 different residues per basket. In contrast, 31 different organic residues were detected in the 21 boiled collard samples, with a mean of only 6 different residues per basket. Thus, collards exhibit a variable residue profile and a much greater residue variety than dry roasted peanuts. Residue profiles of peanuts and peanut butter are, by comparison, predictably consistent. The high incidence and/or variety of residues in leafy vegetables or peanuts is substantiated by previous Total Diet Study findings (1, 2) and by results of other FDA monitoring (3-8, 18, 19) and occurs because of these crops' growth characteristics and/or the type(s) of pesticides applied for control of a wide variety of pests. In the case of peanuts and peanut butter, 6 of as many as 18 different residues can be attributed to 1 pesticide (quintozene), its impurities, and degradation products. Most of the quintozene-related compounds were detected in almost all of the 42 peanut and peanut butter samples.

As Table 2 shows, none of the daily intakes approached established FAO/WHO ADIs. Dieldrin was closest with an intake averaging about 3% of the ADI for the male teen age and young adult male population groups. Note the dramatic decrease in intake from 6 and 5%, respectively, when compared to the 1984-86 period (2).

The dietary intake information presented in Tables 7 and 8 illustrates that for a number of analytes, the majority of the daily intake is derived from a relatively small number of foods. This is true for a number of analytes found in a wide variety of foods, as shown in Table 7. The data demonstrate that in these instances, relatively few foods contribute a high percentage of the total daily intake. Major food types are indicated. Table 8 provides examples of intakes of analytes found in few foods and contributions of specific food(s). The majority of the intakes for these analytes arises from only 1-5 foods out of a total of only 3 to 14 "adult" foods with measurable residues. These findings generally represent uses of pesticides on a limited number of crops.

Table 9 lists the 22 food items in which no organic pesticide-related residues were detected. Note that many of these items are beverages.

Assessment of pesticide residue levels in individual foods reveals that none of the residues approached tolerances applicable to raw agricultural commodities or processed foods; such tolerances are established by the U.S. Environmental Protection Agency (EPA) (20). This is also true for PCB residues in foods of animal origin; the levels detected were below tolerances established by FDA (21).

Total arsenic intakes (expressed as elemental As) are well below the estimated PTDI. Use of the PTDI for mean daily intake comparisons is conservative. In food, arsenic occurs primarily in organic forms; these are relatively non-toxic and represent inconsequential hazards/risks in comparison to the tri and pentavalent inorganic forms.

Dietary intakes of cadmium and mercury do not closely approach their PTDIs. It should be noted that for lead, daily intakes for the 6-11 month infant and the 2-year child, respectively, are well below the PTDI (see Table 4). The PTDI reflects exposure from all sources.

FDA recently proposed PTTILs for lead pertaining to various population groups (22). These levels are applicable to exposure from ingestion only. The PTTILs for young children (0-6 years) and adults (not including pregnant and lactating women) are 6 and 75 $\mu\text{g}/\text{day}$, respectively. Daily lead intakes for this reporting period were 3, 4 and 8 $\mu\text{g}/\text{day}$ for the 6-11 month infant, 2 year child, and 25-30 year male population groups, respectively. These values compare favorably with FDA's PTTILs; current lead intakes are somewhat lower. The dramatic reduction in dietary lead intakes is attributable to elimination of lead-soldered cans in domestic food packaging and other factors, such as use of unleaded gasoline.

Summary and Conclusion

In the 21 market baskets collected during this 5-year reporting period, a total of 113 pesticide,

pesticide-related and industrial chemicals were encountered, compared with nearly 300 that can be detected by the analytical methods utilized. An average of 63 pesticide and industrial chemical residues were found per market basket. The most frequently found organic residues were malathion, an insecticide widely used on fruits, vegetables, and stored products such as grains, and DDE, an environmentally persistent metabolite of DDT. The levels of most pesticide residues found were orders of magnitude lower than residue tolerances applicable to raw agricultural commodities established by EPA; this may be partially attributed to the reductive effect of food preparation, such as cooking and washing, on residue levels. Dietary intakes were far below established ADIs.

Although dietary intakes reported prior to 1982-1984 cannot be compared directly with these findings, it is apparent that intakes of persistent chlorinated pesticides have declined steadily since cessation of their agricultural uses 1 to 2 decades ago. This is best typified by dieldrin, the only pesticide to ever approach its ADI. Today, dieldrin intakes are only a few percent of what they were 20 years ago.

Even though the intakes of persistent chlorinated pesticides and PCBs have declined dramatically, their residues continue to occur at low levels. This is particularly true for foods of animal origin. Although not pervasive, low-level residues of more recently developed pesticides are often detected. The Total Diet Study continues to provide a final check on the effectiveness of the U.S. pesticide regulatory system.

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Table 1. FDA Total Diet food item collections

Collection No.	Date	Location
1 (17) ^a	July 1986	Spokane, WA; Albuquerque, NM; Denver, CO
2 (18)	October 1986	Albany, NY; Providence, RI; Pittsburgh, PA
3 (19)	January 1987	Fargo, ND; Omaha, NB; Memphis, TN
4 (20)	April-May 1987	Brownsville/Harlingen/San Benito, TX; Birmingham, AL; Baton Rouge, LA
5 (21)	July-August 1987	Portland, OR; Fresno, CA; Phoenix, AZ
6 (22)	October 1987	Milwaukee, WI; Indianapolis, IN; Peoria, IL
7 (23)	January 1988	Baltimore, MD; Charleston, SC; Tallahassee, FL
8 (24)	March-April 1988	Reno, NV; Pueblo, CO; El Paso, TX
9 (25)	June-July 1988	Syracuse, NY; Bergen Co. NJ Manchester, NH
10 (26)	August-September 1988	Jackson, MS; Columbus, GA; Ponce, PR
11 (27)	November-December 1988	Akron, OH; Battle Creek, MI; Lincoln, NB
12 (28)	January-February 1989	Nassau/Suffolk, NY; Paterson/Clifton/Passaic, NJ Washington, DC

13 (29)	April-May 1989	Oxnard/Simi Valley/Ventura, CA; Reno, NV; Great Falls, MT
14 (30)	July 1989	Amarillo, TX; Greenville, SC; Biloxi, MS
15 (31)	September-October 1989	Worcester, MA; Binghamton, NY; Allentown/Bethlehem/Easton, PA
16 (32)	January-February 1990	Yakima, WA; Las Vegas, NV; Phoenix, AZ
17 (33)	April 1990	Orlando, FL; Knoxville, TN New Orleans, LA
18 (34)	June-July 1990	Minneapolis, MN; Springfield, IL; Springfield, MO
19 (35)	September 1990	Youngstown, OH Springfield, MA; Harrisburg, PA
20 (36)	November 1990-January 1991	Atlanta, GA; Tampa/St. Petersburg, FL; Houston, TX
21 (37)	April 1991	Green Bay, WI; Detroit, MI; Des Moines, IA

^aFigure shown parenthetically indicates cumulative collection number subsequent to 1982 revision of the Total Diet Study.

Table 2. Mean daily intake per unit of body weight ($\mu\text{g/kg body weight/day}$) in pesticides and industrial chemicals (1986-91)^a

Analyte	FAO/WHO ADI ^b in $\mu\text{g/kg bw/day}$ (percent of ADI) ^c	6-11 mo	2 yr	14-16F	14-16M	25-30F	25-30M	60-65F	60-65M
Acephate		0.0638	0.0099	0.0046	0.0064	0.0082	0.0078	0.0094	0.0086
Aldicarb, total		<0.0001	0.0001	<0.0001	<0.0001	0.0001	<0.0001	<0.0001	<0.0001
Aldicarb	$3 + 4^d$ (<0.003%)	<0.0001	0.0001	<0.0001	<0.0001	0.0001	<0.0001	<0.0001	<0.0001
Azinphos methyl		0.0683	0.0311	0.0061	0.0073	0.0061	0.0079	0.0064	0.0064
BHC, alpha + beta	5 (0.15%)	0.0008	0.0027	0.0011	0.0011	0.0007	0.0008	0.0005	0.0005
BHC, alpha		0.0008	0.0027	0.0011	0.0011	0.0007	0.0008	0.0005	0.0005
BHC, beta		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
BHC, gamma, (lindane)		0.0008	0.0032	0.0014	0.0015	0.0008	0.0010	0.0006	0.0006
Captaf	100 (0.01%)	0.0226	0.0470	0.0129	0.0101	0.0139	0.0072	0.0279	0.0254
Carbaryl	1185	0.1273	0.0302	0.0306	0.0306	0.0338	0.0277	0.0370	0.0320
Carbaryl, total	10 + (<0.001%)	<0.0001	0.0001	<0.0001	<0.0001	0.0001	<0.0001	0.0001	0.0001
Carbofuran		<0.0001	0.0001	<0.0001	<0.0001	0.0001	<0.0001	0.0001	0.0001
3-Hydroxycarbofuran		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Chlordane, total	0.5 + (0.14%)	0.0008	0.0016	0.0007	0.0007	0.0008	0.0008	0.0008	0.0009
Chlordane		0.0002	0.0004	0.0002	0.0002	0.0002	0.0002	0.0003	0.0003
Chlordane, cis		0.0001	0.0001	<0.0001	<0.0001	0.0001	0.0001	0.0001	0.0001
Chlordane, trans		0.0001	0.0001	<0.0001	<0.0001	0.0001	0.0001	0.0001	0.0001
Nonachlor, cis		0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Nonachlor, trans		0.0001	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Oxethlor, isopide		0.0003	0.0008	0.0003	0.0004	0.0003	0.0004	0.0002	0.0003
Chlorobenzilate	20 (0.005%)	0.0030	0.0044	0.0008	0.0010	0.0008	0.0007	0.0008	0.0005
2-Chloroethyl caprate		0.0001	0.0003	0.0003	0.0003	0.0002	0.0003	0.0001	0.0001
2-Chloroethyl fumarate		0.0001	0.0004	0.0003	0.0006	0.0002	0.0003	0.0001	0.0002
2-Chloroethyl linoleate		0.1384	0.2085	0.1404	0.2441	0.0945	0.1764	0.0759	0.1081
2-Chloroethyl myristate		0.0288	0.0057	0.0037	0.0051	0.0029	0.0045	0.0033	0.0034
2-Chloroethyl palmitate		0.0244	0.0458	0.0098	0.0031	0.0211	0.0389	0.0164	0.0240
Chlorobalanol	30 (<0.0003%)	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Chlorobaphan		0.1930	0.5974	0.2428	0.3899	0.1886	0.2319	0.1316	0.1526
Chlorpyrifos	10 (0.05%)	0.0147	0.0138	0.0038	0.0051	0.0038	0.0038	0.0041	0.0040
Chlorpyrifos-methyl	10 (0.17%)	0.0135	0.0323	0.0118	0.0168	0.0101	0.0116	0.0092	0.0107
2,4-D	300 (<0.00003%)	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
DCPA		0.0013	0.0018	0.0007	0.0009	0.0010	0.0009	0.0015	0.0014
DDT, total	20 + (0.10%)	0.0448	0.0438	0.0138	0.0189	0.0106	0.0127	0.0096	0.0104
DDE, Σ p,p'		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
DDE, p,p'		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
DDE, o,p'		0.0441	0.0420	0.0130	0.0181	0.0099	0.0119	0.0082	0.0096
DDE, Σ p,p'		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
DDE, o,p'		0.0004	0.0011	0.0005	0.0005	0.0005	0.0005	0.0006	0.0006
DDE, p,p'		0.0003	0.0003	0.0003	0.0003	0.0002	0.0003	0.0002	0.0002
DEF		<0.0001	0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Diazinon	2 (0.26%)	0.0661	0.0106	0.0037	0.0052	0.0033	0.0037	0.0031	0.0034
Diethionon	4 (<0.002%)	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Dicloran, total	30 (0.17%)	0.2357	0.2586	0.0866	0.0505	0.0773	0.0588	0.1298	0.1113
Dicloran		0.2342	0.2568	0.0860	0.0501	0.0768	0.0588	0.1289	0.1105
2,4-Dichloro-6-nitrobenzamide		0.0015	0.0018	0.0006	0.0004	0.0005	0.0005	0.0009	0.0008
Dicrofol, total	2 + (0.40%)	0.0196	0.0355	0.0076	0.0079	0.0083	0.0055	0.0136	0.0118

Dicofol, Σ g'	0.011	0.022	0.005	0.005	0.005	0.003	0.008	0.007
Dicofol, Σ E	0.015	0.033	0.071	0.074	0.078	0.052	0.128	0.111
Dieldrin	0.057	0.072	0.026	0.030	0.025	0.028	0.027	0.027
Dimethoate	0.138	0.069	0.015	0.017	0.072	0.054	0.039	0.046
Diphenyl 2-ethylhexyl phosphate	1.261	0.446	0.046	0.169	0.294	0.429	0.252	0.2615
Diphenylamine	0.034	0.040	0.073	0.069	0.074	0.051	0.079	0.065
Dieldrin, total	0.001	0.003	0.002	0.002	0.004	0.003	0.004	0.003
Disulfoton	<0.001	0.003	0.002	0.002	0.003	0.002	0.003	0.002
Disulfoton-S sulfone	<0.001	<0.001	<0.001	<0.001	0.001	0.001	0.001	0.001
Disulfoton sulfone	0.044	0.060	0.015	0.010	0.177	0.140	0.024	0.026
Endosulfan, total	0.032	0.076	0.023	0.026	0.030	0.038	0.033	0.033
Endosulfan I	0.169	0.238	0.066	0.058	0.068	0.051	0.099	0.085
Endosulfan II	0.143	0.146	0.062	0.066	0.079	0.103	0.088	0.088
Endosulfan sulfate	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Endrin	0.146	0.222	0.040	0.050	0.045	0.039	0.049	0.035
Ethion, total	0.142	0.216	0.039	0.049	0.034	0.038	0.048	0.034
Ethion oxygen analog	0.004	0.006	0.001	0.001	0.001	0.001	0.001	0.001
Fenitrothion	0.005	0.014	0.004	0.005	0.005	0.008	0.006	0.006
Fenuron ⁵	0.003	0.014	0.002	0.001	0.002	0.002	0.004	0.004
Fenvalerate	0.048	0.044	0.015	0.028	0.017	0.019	0.045	0.042
Folpet	0.018	0.031	0.010	0.007	0.010	0.005	0.022	0.020
Fonflos	<0.001	0.002	<0.001	0.001	<0.001	<0.001	<0.001	<0.001
Gardona	<0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hepachlor, total	0.018	0.001	0.007	0.010	0.007	0.009	0.005	0.007
Hepachlor	<0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Hepachlor epoxide	0.018	0.025	0.007	0.010	0.007	0.009	0.005	0.007
Hexachlorobenzene	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Iprodione, total	0.011	0.021	0.006	0.009	0.006	0.008	0.005	0.006
Iprodione	0.032	0.033	0.011	0.014	0.018	0.021	0.018	0.018
Iprodione metabolite isomer	0.027	0.033	0.007	0.011	0.014	0.009	0.017	0.014
Isopropyl (3-chloro-4-methoxyphenyl) carbamate	0.005	0.018	0.004	0.003	0.004	0.002	0.004	0.004
Isopropyl	0.023	0.056	0.022	0.026	0.019	0.023	0.017	0.019
Linuron	0.018	0.024	0.006	0.007	0.008	0.005	0.008	0.007
Malathion	0.1139	0.2184	0.0686	0.0965	0.098	0.704	0.567	0.665
Metamidophos	0.116	0.199	0.113	0.107	0.167	0.141	0.225	0.180
Metidathion	0.002	0.008	0.002	0.002	0.002	0.002	0.002	0.002
Methiocarb	1 + (0.01%)	<0.001	<0.001	0.001	0.014	0.010	0.006	0.008
Methomyl	30 (0.009%)	0.0123	0.032	0.026	0.037	0.023	0.056	0.049
Methoxychlor, Σ g'	0.004	0.009	0.003	0.004	0.003	0.003	0.001	0.002
Metobromuron ⁶	NC#	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	0.001
Mevinphos, total	0.048	0.078	0.027	0.020	0.030	0.019	0.058	0.052
Mevinphos, cis	0.026	0.042	0.013	0.009	0.014	0.008	0.009	0.006
Mevinphos, trans	0.022	0.036	0.014	0.011	0.016	0.011	0.019	0.026
Monocrotophos	<0.001	<0.001	<0.001	<0.001	0.001	0.001	<0.001	<0.001
Neburon ⁷	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
Omethoate	0.056	0.048	0.014	0.016	0.053	0.040	0.035	0.037
Parathion, total	0.075	0.037	0.011	0.008	0.011	0.009	0.018	0.016
Parathion oxygen analog	0.025	0.037	0.011	0.008	0.011	0.009	0.018	0.016
Parathion-methyl	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
PCBs, total	0.002	0.001	<0.001	<0.001	<0.001	<0.001	0.001	0.001
Pentachlorophenol	0.005	0.019	0.007	0.008	0.006	0.009	0.006	0.006
	0.009	0.014	0.005	0.005	0.008	0.007	0.008	0.008

Permethrin, total	0.1465	0.0707	0.0357	0.0415	0.0565	0.0460	0.0586	0.0592
Permethrin, cis	0.0234	0.0148	0.0179	0.0206	0.0283	0.0231	0.0292	0.0296
Permethrin, trans	0.0231	0.0159	0.0178	0.0209	0.0282	0.0229	0.0294	0.0296
Perthane	0.0067	0.0067	0.0062	0.0063	0.0064	0.0063	0.0065	0.0066
Phorate, total	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Phorate sulfone	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Phorate sulfoxide	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Phosalone	0.0480	0.0042	0.0008	0.0008	0.0007	0.0005	0.0010	0.0009
Phosmet	0.0659	0.0081	0.0021	0.0017	0.0020	0.0016	0.0034	0.0028
Phosphamidon	0.0003	0.0039	0.0007	0.0007	0.0007	0.0005	0.0007	0.0006
Primiphos-methyl	0.0014	0.0041	0.0015	0.0018	0.0016	0.0014	0.0006	0.0007
Profenofos	<0.0001	0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Propargite ^b	0.2812	0.2211	0.0390	0.0487	0.0385	0.0270	0.0473	0.0411
Quintozene, total	0.0008	0.0025	0.0066	0.0010	0.0006	0.0008	0.0003	0.0007
Penachlorobenzene	0.0003	0.0010	0.0002	0.0004	0.0002	0.0003	0.0002	0.0003
Penachlorobenzonitrile	0.0001	0.0003	0.0001	0.0001	0.0001	0.0001	<0.0001	<0.0001
Penachlorophenyl methyl ether	0.0001	0.0005	<0.0001	0.0002	<0.0001	0.0002	<0.0001	<0.0001
Penachlorophenyl methyl sulfide	0.0001	0.0001	0.0001	0.0002	0.0001	0.0001	<0.0001	<0.0001
Quintozene	0.0001	0.0003	0.0001	0.0001	0.0001	0.0001	<0.0001	<0.0001
Sulfur	0.0064	0.0268	0.0055	0.0051	0.0053	0.0031	0.0069	0.0068
Tecnazene, total	0.0001	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Tecnazene	0.0001	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
2,3,5,6-Tetrachloroaniline	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
2,3,5,6-Tetrachloroanisidine	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Terbufos	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Thiobenzazolin ^c	0.2461	0.6685	0.1326	0.1655	0.1506	0.1139	0.1853	0.1432
Tosaphene	0.0071	0.0224	0.0062	0.0089	0.0057	0.0067	0.0078	0.0077
Triallate	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001
Tri (2-butoxyethyl) phosphate	0.0052	0.0037	0.0012	0.0011	0.0020	0.0009	0.0034	0.0028
Tributyl phosphate	0.0030	0.0025	0.0005	0.0007	0.0003	0.0003	0.0004	0.0004
Tri (2-ethylhexyl) phosphate	0.0015	0.0051	0.0029	0.0033	0.0039	0.0055	0.0033	0.0037
Triphenyl phosphate	0.0157	0.0348	0.0163	0.0182	0.0128	0.0184	0.0114	0.0158
Tris (chloroethyl) phosphate	0.0001	0.0002	0.0001	0.0001	0.0001	0.0001	0.0001	0.0001
Vinidolzin	0.0059	0.0110	0.0031	0.0024	0.0035	0.0018	0.0069	0.0062

^a Total number of pesticide, industrial chemical and other organic residues detected = 113.

^b FAO/WHO ADIs are expressed in these terms for ease of comparison; ADIs are usually expressed in terms of mg/kg b.w./day.

^c Percent of ADI based on daily intake of 14-16 year male.

^d + denotes compounds for which the ADI includes other (retired) chemicals

^e Reported on the basis of phenylurea analysis of 20 selected foods in 5 market baskets and 14 foods in 1 market basket.

^f Temporary ADI.

^g No consumption of any food item containing this residue in this age/sex group

^h Reported values based on usage of a sulfur-selective detector for selected foods in 12 market baskets (39 foods were covered in 7 market baskets and 50 foods were covered in 5 market baskets)

Table 3. Frequency of Occurrence of Pesticide Residues in Total Diet Study (1986-1991)

Pesticide	Total No. of Findings ^a	Occurrence, %
Malathion	981	20
DDE, p,p'	806	16
Diazinon	539	11
Chlorpyrifos	440	9
Chlorpyrifos-methyl	440	9
Dieldrin	419	8
Endosulfan ^b	343	7
Methamidophos	284	6
Hexachlorobenzene	278	6
Dicloran	237	5
Chlorpropham	197	4
Heptachlor epoxide	188	4
Lindane	185	4
Carbaryl ^c	169	3
Acephate	167	3
Dimethoate	138	3
Ethion	115	2

^a Based on 4914 items.

^b Includes endosulfan I, endosulfan II, and endosulfan sulfate.

^c Reflects overall incidence; however, only 72 selected foods per market basket (i.e., 1512 total items) were analyzed for N-methylcarbamates.

Table 4. Mean daily intake ($\mu\text{g}/\text{kg}$ body weight/day) of selected elements (1986-1991)

Element	Age group	PTDI ^a in		2 yr	14-16F	14-16M	25-30F	25-30M	60-65F	60-65M
		$\mu\text{g}/\text{kg}$ b.w./day	6-11 mo							
Arsenic ^b	adults	2.1 ^c	0.50	0.81	0.36	0.39	0.44	0.51	0.46	0.48
Cadmium	adults	1.0 ^d	0.36	0.46	0.17	0.22	0.16	0.17	0.14	0.15
Lead	infants, children and adults	3.6 ^d	0.37	0.30	0.10	0.12	0.10	0.10	0.10	0.09
Mercury, total ^c	adults	0.71 ^d	0.04	0.07	0.03	0.03	0.04	0.04	0.04	0.03

^aPTDI = Provisional tolerable daily intake.^bExpressed as inorganic arsenic. Use of the PTDI for mean daily intake comparisons is conservative. In food, arsenic occurs primarily in organic forms; these are relatively non-toxic and represent inconsequential hazards/risks in comparison to the tri and pentavalent inorganic forms.^cThere has been no agreement on a maximum acceptable intake for total (organic and inorganic) arsenic. However, the FAO/WHO (16) has assigned a PTDI for inorganic arsenic of 2.1 $\mu\text{g}/\text{kg}$ body weight.^dPTDIs calculated from the Provisional Tolerable Weekly Intakes proposed by the FAO/WHO (13,15).^eMeasured as total mercury, which includes both inorganic and organic forms. An organic form of mercury would predominate (e.g., methyl mercury), since most of the mercury reported in the TDS originates from seafood where the prevalent form is methyl mercury.

Table 5. Comparison of 1982-84, 1984-86 and 1986-91 mean daily intakes per unit of body weight ($\mu\text{g/kg}$ body weight/day) for selected chemicals and population groups

Residue	Children						Adults					
	6-month-old			2-year-old			14-16 year male			25-30 year male		
	82/84	84/86	86/91	82/84	84/86	86/91	82/84	84/86	86/91	82/84	84/86	86/91
Carbaryl	0.11	0.07	0.12	0.12	0.06	0.13	0.02	0.009	0.03	0.02	0.01	0.03
DDT, total	0.10	0.05	0.04	0.10	0.05	0.04	0.04	0.02	0.02	0.03	0.02	0.01
Diazinon	0.01	0.002	0.006	0.03	0.005	0.01	0.01	0.002	0.005	0.009	0.002	0.004
Dieldrin	0.01	0.01	0.006	0.02	0.01	0.007	0.008	0.005	0.003	0.007	0.004	0.003
Heptachlor epoxide	0.003	0.003	0.002	0.006	0.004	0.002	0.003	0.002	0.001	0.002	0.002	0.001
Hexachlorobenzene	0.002	0.003	0.001	0.005	0.005	0.002	0.002	0.002	0.001	0.002	0.002	0.001
Malathion	0.14	0.13	0.11	0.23	0.26	0.22	0.11	0.12	0.10	0.07	0.08	0.07
Parathion	0.01	0.008	0.008	0.005	0.003	0.004	0.001	0.001	0.001	0.001	0.001	0.001
PCBs, total	0.001	0.001	<0.001	0.001	0.002	0.002	<0.001	0.002	<0.001	<0.001	0.001	<0.001
Cadmium	0.46	0.50	0.36	0.56	0.60	0.46	0.26	0.27	0.22	0.20	0.20	0.17
Lead	1.86	1.11	0.37	1.77	0.99	0.30	0.69	0.36	0.12	0.54	0.28	0.10

Table 6. Number of different organic residues in selected Total Diet foods (1986-91)

Food item	Total no. of different residues	Mean no. of different residues/basket
Collards (fresh/frozen), boiled	31	6
Peaches, raw	31	6
Cucumbers, raw, pared	28	6
Squash, summer (fresh/frozen), boiled	28	6
Spinach (fresh/frozen), boiled	28	7
Cherries, sweet, raw	26	5
Strawberries, raw	23	5
Raisins	23	5
Sweet peppers, green, raw	22	6
Squash, winter (Hubbard/acorn), fresh/frozen, boiled	22	3
Grapes (purple/green), raw	22	4
Pears, raw	21	4
Apples, red with peel, raw	20	6
Baked potatoes with peel	20	4
Lettuce, raw	19	3
Celery, raw	19	6
Plums, purple, raw	19	3
Peanuts, dry roasted in jar, salted	18	12
Beans, snap green (fresh/frozen), boiled	18	3
Potato chips	17	3
Tomatoes, raw	17	4
Hamburger, ¼ lb, on white roll with garnish	17	5
Beef and vegetable stew, homemade	17	3
Scalloped potatoes	17	3
Boiled potatoes without peel	17	2
Broccoli (fresh/frozen), boiled	16	2
Pizza, cheese, frozen, commercial, heated	16	5
Peanut butter, creamy	16	10
Meatloaf, beef, homemade	16	3
Pumpkin pie, frozen, heated	16	6
Pickles, dill, bottled	16	4
Cantaloupe, raw	16	3
Radishes, raw	15	2

Table 7. Percent total average daily intake (25-30 year male) from foods/food types for some frequently found analytes (1986-91)

Analyte	No. of adult foods ^a with residues	Total µg/day	µg from major contributing foods (no.)	% of total daily intake	Major contributing product types
Arsenic	117	38.6	34.1 (4)	88	seafood
Cadmium	163	12.9	10.3 (37)	80	grain, potato, lettuce
Chlorpyrifos	90	0.292	0.194 (12)	66	apples, vegetables, bread
DDE, DDT	105	0.904	0.559 (10)	62	meat, dairy
Dieldrin	51	4.47	3.87 (3)	87	fruit, sweet potatoes
Dieldrin	77	0.211	0.170 (18)	81	meat, dairy
Heptachlor epoxide	51	0.066	0.048 (10)	73	meat, dairy
Hexachlorobenzene	48	0.062	0.047 (11)	76	meat, dairy
Lead	138	7.61	6.19 (34)	81	dispersed
Lindane	59	0.075	0.050 (5)	67	meat, dairy, chocolate
Malathion	83	5.35	4.65 (17)	87	grain-based
Mercury	177	2.79	2.40 (4)	86	seafood

^aTotal no. of adult foods = 201.

8. Percent total average daily intake (25-30 year male) from... foods/food types for some infrequently found analytes (1986-1991)

Analyte	No. of adult foods ^a with residues	Total µg/day	µg from major contributing foods (no.)	% of total daily intake	Major contributing product types
Azinphos-methyl	6	0.336	0.332 (3)	99	pome and stone fruits
Captan	8	0.550	0.464 (1)	84	strawberries
Chlorobenzilate	4	0.055	0.048 (1)	87	orange juice
Ethion, total	14	0.296	0.255 (3)	86	orange juice and drink, pears
Linuron	3	0.040	0.039 (1)	98	carrots
Phosmet	4	0.119	0.113 (2)	95	peaches, pears
Tecnazene	9	0.006	0.005 (5)	83	potato
Toxaphene	11	0.508	0.344 (2)	68	peanut
Vinclozolin	5	0.139	0.116 (1)	83	strawberries

^aTotal no. of adult foods = 201.

Table 9. Total Diet food items in which no organic pesticide-related residues were detected (1986-1991)

Bananas and pineapple with tapioca (st/jr) ^a
Beef bouillon, canned, reconstituted with water
Coffee beverage, prepared from instant
Coffee beverage, prepared from instant, decaffeinated
Corn, canned
Corn, cream style, canned
Corn flakes
Cream substitute, powdered
Infant formula, milk-based without iron, canned, ready-to-serve
Margarine, stick type
Peas, green, canned
Peas (st/jr)
Pineapple, canned in juice pack
Pineapple juice, canned
Pudding/custard, any flavor (st/jr)
Salad dressing, Italian, bottled
Soda, sweetened, cola type, canned
Soft drink, made from powder, cherry flavor, presweetened
Sugar, white, granulated
Syrup, pancake, bottled
Water
Whiskey, 80 proof

^ast/jr = strained/junior



FDA MONITORING PROGRAM

Three federal government agencies share responsibility for the regulation of pesticides (1). The Environmental Protection Agency (EPA) registers (i.e., approves) the use of pesticides and sets tolerances (the maximum amount of a residue that is permitted in or on a food) if use of that particular pesticide may result in residues in or on food (2). Except for meat, poultry, and certain egg products, for which the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible, FDA is charged with enforcing tolerances in imported foods and in domestically produced food shipped in interstate commerce. FDA also acquires incidence/level data on particular commodity/pesticide combinations and carries out its annual market basket survey, the Total Diet Study. In 1990, USDA's Agricultural Marketing Service (AMS) initiated, through contracts with participating states, a residue testing program directed primarily at raw agricultural products (fruits and vegetables). FSIS and AMS pesticide residue data are reported independently by those agencies.

REGULATORY MONITORING

One aspect of FDA's monitoring program involves the sampling of individual lots of domestically produced and imported foods and analysis of these foods for pesticide residues. Domestic samples are collected as close as possible to the point of production in the distribution system; import samples are collected at the point of entry into U.S. commerce. Emphasis is on the raw agricultural product, which is analyzed as the unwashed, whole, raw commodity, that is, with the peel or skin intact. Processed foods are also included. If illegal residues (above EPA tolerance or no tolerance for that particular food/pesticide combination) are found in domestic samples, FDA can invoke various sanctions, such as a seizure or injunction. For imports, shipments may be stopped at the port of entry when

illegal residues are found. "Automatic detention" may be invoked for imports based on the finding of 1 violative shipment if there is reason to believe that the same situation will exist in future lots during the same shipping season for a specific shipper, grower, geographic area, or country.

The food samples collected are classified as either "surveillance" or "compliance." Most samples that FDA collects are the surveillance type; that is, there is no prior knowledge or evidence that a specific food shipment contains illegal pesticide residues. Compliance samples are taken as follow-up to the finding of an illegal residue or when there is other evidence of a pesticide residue problem.

FDA establishes monitoring priorities through development of an annual National Sampling Plan, which is a compilation of 6 Regional Sampling Plans prepared by FDA personnel throughout the United States. Each annual Plan is designed to provide for sampling and pesticide residue analyses of domestic and imported foods of dietary importance, including products from approximately 80 countries, all 50 states, and Puerto Rico. Some deviations from the Plan may occur depending on circumstances in the individual FDA Districts.

Factors considered in preparing the Sampling Plan include review of recently generated FDA residue data and those produced by the states, regional intelligence on pesticide use, dietary importance of the food, information on the amount of imported food and domestic food that enters interstate commerce, chemical characteristics and toxicity of the pesticide, and production volume/pesticide usage patterns.

ANALYTICAL METHODS

To analyze the large numbers of samples whose pesticide treatment history is usually unknown, analytical methods capable of simultaneously determining a number of pesticide residues are used. These multiresidue methods (MRMs) can determine about half of the approximately 300 pesticides with EPA tolerances, and many others that have no tolerances. The most

commonly used MRMs can also detect many metabolites, impurities, and alteration products of pesticides with and without tolerances (3).

Single residue methods (SRMs) or selective MRMs are used to determine pesticides not covered by an MRM (3). An SRM usually determines 1 pesticide; a selective MRM measures a relatively small number of chemically related pesticides. These types of methods are usually more resource-intensive per residue, and they may require at least as much time to perform as an MRM. They are much less cost efficient than MRMs.

The lower limit of residue measurement in FDA's determination of a specific pesticide is usually well below tolerance levels, which generally range from 0.1 to 50 parts per million (ppm). Residues present at 0.01 ppm and above are usually measurable; however, for individual pesticides, this limit may range from 0.005 to 1 ppm. In this report, the term "trace" is used to indicate residues detected, but at levels below the limit of quantitation.

FDA/STATE COOPERATION

Personnel in FDA field offices interact with their counterparts in most states to carry out more effective pesticide residue monitoring. The extent of these cooperative efforts varies among the states and depends on the size and scope of the pesticide program in the individual states, i.e., states in which agriculture is a major industry tend to have greater resources and more personnel devoted to agriculture-related programs.

FDA also acquires and uses state-generated pesticide residue data to complement its own and other federally sponsored residue programs. For many years, FDA has supported, through a contract with Mississippi State University (MSU), the "Foodcontam" database, which is a compilation of state-collected residue data.

ANIMAL FEEDS

In addition to monitoring foods for human consumption, FDA also samples and analyzes domestic and imported feeds for pesticide residues. This monitoring

is carried out under the direction of FDA's Center for Veterinary Medicine (CVM) via its Feed Contaminants Compliance Program.

CVM also reviews pesticide residue data supplied by various states under "Feedcon," a database operated by MSU under the auspices of the Association of American Feed Control Officials. These data are reviewed periodically by CVM so that potential problems stemming from pesticide residues in foods of animal origin may be identified.

INTERNATIONAL ACTIVITIES

FDA has obtained information on foreign pesticide usage via contract for several years. Under the current contract with Landell Mills (Bath, England), FDA receives pesticide usage data each year for about 30 countries that export food to the United States. These data allow FDA to more accurately target particular pesticide/commodity/country combinations for monitoring.

In 1993, FDA continued to work with foreign governments and food producers to promote pesticide usage practices for foreign-grown foods that are consistent with U.S. registrations and tolerances. In some of these activities, FDA worked closely with staffs from EPA, USDA, and the Agency for International Development (AID) to assist foreign producers and governments in developing countries in understanding the U.S. pesticide regulatory system and in establishing their own pesticide regulatory infrastructure.

These programs were focused primarily on Central America. The activities included work with Guatemalan government and industry officials to establish pesticide usage control and oversight for snowpeas and other vegetables to ensure better compliance of Guatemalan exports with U.S. tolerances. In addition, a multiagency effort by FDA, EPA, and AID was continued throughout Central America to establish new analytical laboratories and improve existing ones so that Central American food exports to the United States and elsewhere could be monitored for compliance with residue tolerances.

It is important to note that the results of the analysis suggest that the probability of a firm's being a supplier of a high-tech product is not a function of the firm's size and industry. These findings

FIGURE 1. Summary of results of monitoring of pesticide residues in food samples collected from 1990 to 1992. (a) Pesticide residues in food samples collected from 1990 to 1992.

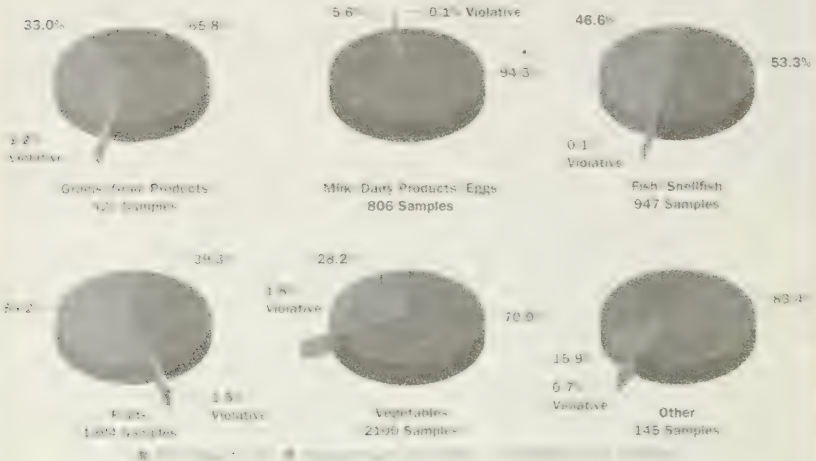
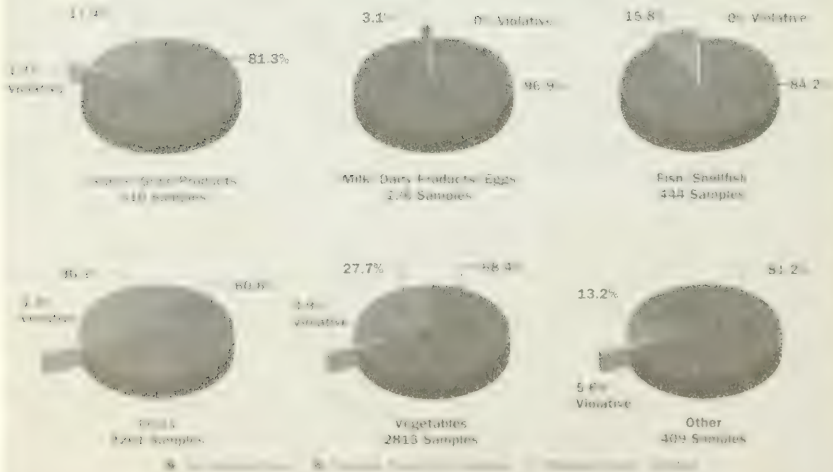


FIGURE 2. Summary of results of monitoring of pesticide residues in food samples collected from 1990 to 1992. (b) Pesticide residues in food samples collected from 1990 to 1992.



concentrations are high, their effect on the population is reduced. Thus, the degree of the inhibition of the growth of the population is directly related to the growth rate of the population. The effect of the growth rate of the population on the degree of the inhibition of the growth of the population is directly related to the growth rate of the population. The effect of the growth rate of the population on the degree of the inhibition of the growth of the population is directly related to the growth rate of the population.

Results and Discussion

RESULTS AND DISCUSSION

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Figure 10.10 illustrates the relationship between the number of employees and the number of managers. The relationship is not linear, and the number of managers increases at a decreasing rate as the number of employees increases. This is a characteristic of a power law relationship, which is a type of non-linear relationship. The relationship can be described by the equation $M = 0.0001E^2$, where M is the number of managers and E is the number of employees. This equation shows that the number of managers increases with the square of the number of employees, which is a non-linear relationship.

TABLE 1. FOREIGN COUNTRIES AND NUMBER OF SAMPLES^a COLLECTED AND ANALYZED IN 1993

Country	No. of Samples	Country
Mexico	1820	Ten or fewer samples collected from the following:
Chile	612	Bahamas
Canada	368	Bangladesh
Thailand	271	Barbados
The Netherlands	268	Belize
Italy	241	Bolivia
China, People's Rep. of	234	Bosnia-Herzegovina
Guatemala	212	British Indian Ocean Terr.
Dominican Republic	177	British Virgin Islands
New Zealand	173	Bulgaria
Costa Rica	164	Burma
Spain	164	Cayman Islands
Honduras	154	Croatia
India	126	Czechoslovakia
Colombia	118	Dem. People's Rep. of Korea
Jamaica	103	Ethiopia
Argentina	93	Faeroe Islands
Belgium	87	Fiji
Greece	69	Finland
Ecuador	62	Ghana
Brazil	61	Greenland
Peru	59	Guyana
Taiwan	59	Ireland
Indonesia	58	Ivory Coast
Turkey	58	Jordan
Korea, Rep. of	52	Kenya
Venezuela	49	Liberia
Germany	48	Liechtenstein
Japan	47	Lithuania
Australia	46	Luxembourg
Israel	44	Macedonia
France	40	Madagascar
United Kingdom	40	Malawi
Portugal	38	Malaysia
Trinidad & Tobago	38	Mozambique
Philippines	37	Netherlands Antilles
Hong Kong	29	Nigeria
Denmark	27	Norway
Uruguay	26	Oman
Haiti	24	Papua New Guinea
El Salvador	22	Russia
Lebanon	22	Saudi Arabia
Pakistan	21	Slovenia
Grenada	19	South Africa
Panama	18	Soviet Union (former)
Hungary	17	Sri Lanka
Poland	17	St. Helena
Austria	16	St. Lucia
Morocco	16	Surinam
Iceland	15	Sweden
Singapore	14	Tanzania
Nicaragua	13	Tonga
Switzerland	13	Yugoslavia (former)
Egypt	12	
Unspecified	17	

^a Surveillance plus compliance samples.

TABLE 2. (cont'd) PESTICIDES DETECTABLE BY THE METHODS USED AND PESTICIDES FOUND (*) IN 1993 REGULATORY MONITORING^{a,b}

Pesticide	Pesticide	Pesticide	Pesticide
Cypermethrin*	Famphur	Methabenzthiazuron	Pirimicarb
Cyprazine	Fenamiphos	Methamidophos*	Pirimiphos ethyl
Daminozide	Fenarimol	Methazole	Pirimiphos:methyl*
DCPA*	Fenbuconazole	Methidathion*	Pretlathlor
DDT*	Fenfuram	Methiocarb*	Probenazole
DEF*	Fenitrothion*	Methomyl*	Prochloraz
Deltamethrin	Fenobucarb	Methoprotrolyne	Procyazine
Deltamethrin, trans	Fenoxaprop ethyl ester	Methoxychlor*	Procymidone*
Demeton*	Fenoxycarb	Methylene chloride	Prodiamine
Dialiflor	Fenpropathrin	Metobromuron	Profenofos*
Di-allate	Fenpropimorph	Metolachlor	Profluralin
Diazinon*	Fenson	Metolcarb	Promecarb
Dicamba	Fensulfotiothion	Metribuzin	Prometryn
Dichlobenil*	Fenthion*	Mevinphos*	Pronamide*
Dichlofenthion	Fenvalerate	Mirex*	Propachlor
Dichlofluanid	Flamprop-M-isopropyl	Monocrotophos*	Propanil
Dichlorone	Flamprop-methyl	Monolinuron	Propargite*
Dichlorvos*	Fluazifop butyl ester	Myclobutanil*	Propazine
Diclobutrazol	Fluchloralin	Naled	Propetamphos
Diclofop-methyl	Flucythrinate	Napropamide	Propham
Dicloran*	Flusilazole	Neburon	Propiconazole
Dicofol*	Fluvalinate	Nitralin	Propoxur
Dicrotophos*	Folpet*	Nitrapyrin	Prothiofos
Dieltin*	Fonofos*	Nitrofen	Prothoate
Diethyl-ethyl	Formetanate hydrochloride*	Nitrofluorfen	Pyrazon
Dimethachlor	Formothion	Nitrothial-isopropyl	Pyrazophos
Dimethametryn	Gardona	Norflurazon	Pyrethrins
Dimethoate*	Haloxyfop	Nuanimol	Pyridaphenthion
Dinitramine	Heptachlor*	Ochlinone	Quinalphos*
Dinobuton	Heptenophos	Ofurace	Quintozene*
Dinocap	Hexachlorobenzene*	Omethoate*	Quazalofop ethyl ester
Dioxabenzofos	Hexaconazole	Ovex	R25788
Dioxacarb	Hexazinone	Oxadiazon*	Ronnel
Dioxathion	Imazalil*	Oxadixyl	Schradan
Diphenamid	Imazamethabenz methyl	Oxamyl*	Simazine
Diphenylamine*	ester	Oxycarboxin	Simetryn
Disulfoton*	Iprobenfos	Oxydemeton-methyl	Strobane
Diuron	Iprodione*	Oxyfluorfen	Sulfalate
Edifenphos	Isazofos	Oxythioquinox	Sulfotep*
Endosulfan*	Isafenphos	Paclobutrazol	Sulfur dioxide*
Endrin*	Isoprocab	Parathion*	Sulphenone
EPN*	Isopropalin	Parathion-methyl*	Sulprofos
EPTC	Isoprotiothane	Pebulate	TCMFB
Esfenvalerate*	Lactofen	Penconazole	TDE*
Etaconazole	Lambda-cyhalothrin	Pendimethalin	Tebupirifos*
Ethalfuralin	Leptophos	Permethrin*	Tecnazene
Ethiofencarb	Lindane*	Perthane	TEPP
Ethion*	Linuron*	Phenothrin	Terbacil
Ethofumesate	Malathion*	Phenthoate	Terbufos*
Ethoprop*	MCPA	Phenylphenol, ortho	Terbumeton
Ethoxyquin	Mecarbam*	Phorate*	Terbutylazine
Ethylenebisdithiocarbamates.*	Mephosfolan	Phosalone*	Terbutryn
Ethylene dibromide	Merphos	Phosmet*	Tetraodon*
Ethylene dichloride	Metallaxyl	Phosphamidon*	Tetraiodoethylene
Etridazole	Metasystox thiol	Pipernyl butoxide	Tetrasul
Etrifosfos	Metazachlor	Piperophos	Triabendazole*

^a Federal Data Administration Pesticide Program ■ Research Methods ■ 1993

TABLE 2

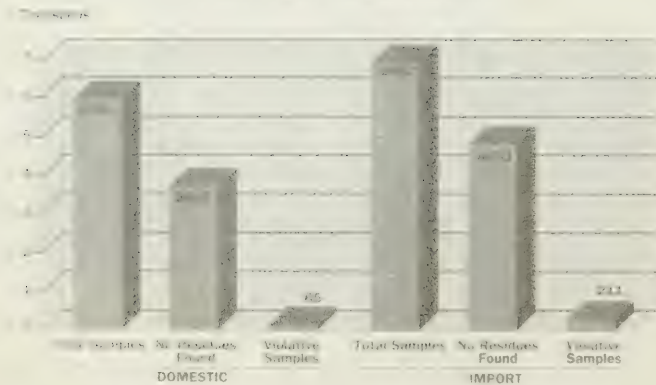
Location	Food or Feed	Exposure to Residues	Exposure to Residues	Exposure to Residues
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food

GLOBAL STUDY

Global studies of pesticide residues in food and feed have been conducted in many countries. The results of these studies have shown that pesticide residues are present in food and feed in many countries. The levels of residues are generally low, but they can be higher in some countries. The results of these studies have also shown that pesticide residues are present in food and feed in many countries. The levels of residues are generally low, but they can be higher in some countries.

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Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food
Domestic	Food	Food	Food	Food

TABLE 3
Pesticide Residues in Food and Feed in the United States
Data from the National Pesticide Survey

SIMILAR REPLICABLE MONITORING

Monitoring and evaluation are essential to the success of any project. The purpose of monitoring is to provide a systematic and regular collection of data on the progress of the project, and to provide a basis for the evaluation of the project. The purpose of evaluation is to provide a systematic and regular collection of data on the impact of the project, and to provide a basis for the improvement of the project. The purpose of monitoring and evaluation is to provide a systematic and regular collection of data on the progress and impact of the project, and to provide a basis for the improvement of the project.

The purpose of monitoring and evaluation is to provide a systematic and regular collection of data on the progress and impact of the project, and to provide a basis for the improvement of the project.

1. PURPOSE OF MONITORING

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2. PURPOSE OF EVALUATION

The purpose of evaluation is to provide a systematic and regular collection of data on the impact of the project, and to provide a basis for the improvement of the project.

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STATISTICALLY BASED MONITORING SURVEY

Pears. The original goal of the project had been to collect 1600 samples of pears (800 domestic and 800 import). For pears, 710 domestic and 949 import samples (these numbers are not included in the counts under Fruits in Appendixes A and B) were collected from 179 pear establishments and analyzed using both MRMs and SRMs. The number of domestic samples is less than planned because some of the targeted firms were no longer in business or pears were not available from a particular firm at the time of FDA's collection visits. The violation rate for the 710 domestic samples was 0.4%, and for the 949 import samples it was 1.3% (FDA, unpublished data, 1994).

Tomatoes. As with the pears, 1600 samples were to be collected (800 domestic and 800 import). However, for the same reasons as noted above for the pears, the numbers of samples varied from those targeted. A total of 1219 domestic and 144 import samples (these numbers are not included in the counts under Vegetables in Appendixes A and B) were collected from 10 packers and 240 repackers and analyzed using both MRMs and SRMs. The violation rate for the 1219 domestic samples was 2.7% and for the 144 import samples it was 3.5% (FDA, unpublished data, 1994).

The violation rates for these 2 commodities for 1993 surveillance samples were pears, domestic, 4%; imports, 10%; and for tomatoes, domestic, 3%; imports, <1% (Appendixes A and B). In some instances, the violation rates found under statistically based monitoring are considerably lower than those found under regulatory monitoring (surveillance samples) mainly because sampling under the latter approach is somewhat biased. (A detailed report describing the statistically based survey and the results is in preparation.)

SUMMARY: INCIDENCE/LEVEL MONITORING

The findings obtained under this approach, which included the analysis of 308 samples of aquaculture products and 308 samples of milk, were consistent with those obtained under regulatory monitoring. Residues in the aquaculture products and whole milk were, with the exception of no-tolerance residues of 3 pesticides in several catfish samples, within regulatory limits. A statistically based monitoring survey of domestic and imported pears and tomatoes was completed in 1993.

TOTAL DIET STUDY

The Total Diet Study is unique in that it determines pesticide residues in foods which have been prepared as they would be consumed (4). Of the nearly 300 chemicals that can be determined by the analytical methods used, 99 pesticide and pesticide-related chemicals were found in the foods analyzed in the 6 collections between September 1991 and July 1993. To measure the low levels of pesticides found in the Total Diet Study foods, the analytical methods used are modified to permit measurement at levels 5-10 times lower than those normally used in regulatory monitoring. In general, residues present at or above 1 part per billion can be measured.

Table 8 lists the 19 most frequently found residues, with the total number of findings and the percent occurrence in the 1566 food items analyzed during the 1991-1993 period. Malathion, which is used on a wide variety of crops both pre- and postharvest, was the most frequently found residue. Low levels of DDT residues (principally *p,p'*-DDE) associated with animal-derived foods were the next most prevalent. Table 9 lists the 29 Total Diet Study food items in which no organic pesticide-related residues were found. A large number of these items are beverages. An even larger number of these "no-residue" foods are either strained or junior foods intended for infants and children or foods consumed in significant amounts by infants and children. An extensive review of FDA's monitoring of pesticide residues in infant foods and adult foods

SUMMARY: TOTAL DIET STUDY

In the 1991-1993 period, the types of pesticide residues found in the Total Diet Study and their frequencies of occurrence are consistent with those given in other FDA reports (5-10,15). Pesticide residue levels were generally very low; 29 food items had no pesticide-related residues detected in the 1991-1993 period assessed. The data for 1993 continue to indicate that consumer exposure to pesticide residues from foods is very low.

SUMMARY

A total of 12,751 samples of domestically produced food from all 50 states and Puerto Rico and imported food from 107 countries was analyzed for pesticide residues in 1993. Of these, 12,166 were surveillance samples, which are collected when there is no evidence of a pesticide problem. No residues were found in 64% of the domestic surveillance samples and 69% of the import surveillance samples. Findings in the 585 compliance samples reflect the fact that they are collected and analyzed when a pesticide problem is suspected. Under incidence/level monitoring, 308 samples of aquaculture seafood/shellfish and 308 milk samples were analyzed for pesticide residues. The findings were similar to those from FDA's regulatory monitoring. In addition, a statistically based monitoring survey of pears and tomatoes was completed in 1993. Low violation rates were found for both the domestic and import segments of the 2 commodities. The types of residues found in the Total Diet Study for 1991-1993 were similar to those found in earlier periods.

This report was compiled through the efforts of the following FDA personnel: Norma J. Yess, Marcia G. Houston, Ellis L. Gunderson, Young H. Lee, and Byron O. Bohannon, Office of Plant and Dairy Foods and Beverages, Division of Programs and Enforcement Policy, and Sharon A. Schoen, Office of Management Systems, Division of Information Resources Management, Washington, DC.

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FDA pesticide monitoring data collected under the regulatory monitoring approach in 1993 are available for purchase on personal computer diskettes from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (telephone 703-487-4650; order number PB94-501681).

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**APPENDIX A. ANALYSIS OF DOMESTIC SURVEILLANCE SAMPLES BY
COMMODITY GROUP IN 1993**

Commodity Group	Total No. of Samples	Samples with No Residues Found, %	Samples Violative, %	
			Over Tolerance	No Tolerance
A. Grains and Grain Products				
Barley	15	60	0	0
Corn & corn products	65	63	0	0
Oats	17	59	0	0
Rice & rice products	94	90	0	3
Soybeans	60	85	0	0
Wheat	146	45	<1	<1
Cereal products	13	77	0	0
Other grains & grain products	11	45	0	0
Total	421	66	<1 ^a	<1
B. Milk/Dairy Products/Eggs				
Cheese/cheese products	124	94	0	0
Eggs	265	96	0	0
Milk & cream/milk products	417	93	0	<1
Total	806	94	0	<1
C. Fish/Shellfish				
Total	947	53	<1	0
D. Fruits				
Blueberries	28	54	0	4
Grapes	55	80	0	0
Raspberries	19	63	0	11
Strawberries	118	29	0	<1
Other berries	18	44	0	0
Grapefruit	28	36	0	0
Lemons	15	20	0	0
Oranges	122	21	0	0
Other citrus fruits	25	20	0	0
Apples	312	39	0	<1
Pears	26	8	0	4
Apricots	31	6	0	6
Cherries	80	15	0	0
Nectarines	35	14	0	6
Peaches	134	20	4 ^a	<1
Other pit fruits	24	71	0	0
Kiwi fruit	20	100	0	0
Papayas	22	91	0	0
Pineapples	13	100	0	0
Other tropical fruits	7	86	0	0

TABLE 1. (continued) *Phragmites australis* (Cav.) Trin. ex Steud. in the Sacramento-San Joaquin River Delta, California, 1997-1998

Site name	Area (ha)	Number of plots	Number of plots with standing water
1. Delta	1,000	100	100
2. Delta	1,000	100	100
3. Delta	1,000	100	100
4. Delta	1,000	100	100
5. Delta	1,000	100	100
6. Delta	1,000	100	100
7. Delta	1,000	100	100
8. Delta	1,000	100	100
9. Delta	1,000	100	100
10. Delta	1,000	100	100
11. Delta	1,000	100	100
12. Delta	1,000	100	100
13. Delta	1,000	100	100
14. Delta	1,000	100	100
15. Delta	1,000	100	100
16. Delta	1,000	100	100
17. Delta	1,000	100	100
18. Delta	1,000	100	100
19. Delta	1,000	100	100
20. Delta	1,000	100	100
21. Delta	1,000	100	100
22. Delta	1,000	100	100
23. Delta	1,000	100	100
24. Delta	1,000	100	100
25. Delta	1,000	100	100
26. Delta	1,000	100	100
27. Delta	1,000	100	100
28. Delta	1,000	100	100
29. Delta	1,000	100	100
30. Delta	1,000	100	100
31. Delta	1,000	100	100
32. Delta	1,000	100	100
33. Delta	1,000	100	100
34. Delta	1,000	100	100
35. Delta	1,000	100	100
36. Delta	1,000	100	100
37. Delta	1,000	100	100
38. Delta	1,000	100	100
39. Delta	1,000	100	100
40. Delta	1,000	100	100
41. Delta	1,000	100	100
42. Delta	1,000	100	100
43. Delta	1,000	100	100
44. Delta	1,000	100	100
45. Delta	1,000	100	100
46. Delta	1,000	100	100
47. Delta	1,000	100	100
48. Delta	1,000	100	100
49. Delta	1,000	100	100
50. Delta	1,000	100	100
51. Delta	1,000	100	100
52. Delta	1,000	100	100
53. Delta	1,000	100	100
54. Delta	1,000	100	100
55. Delta	1,000	100	100
56. Delta	1,000	100	100
57. Delta	1,000	100	100
58. Delta	1,000	100	100
59. Delta	1,000	100	100
60. Delta	1,000	100	100
61. Delta	1,000	100	100
62. Delta	1,000	100	100
63. Delta	1,000	100	100
64. Delta	1,000	100	100
65. Delta	1,000	100	100
66. Delta	1,000	100	100
67. Delta	1,000	100	100
68. Delta	1,000	100	100
69. Delta	1,000	100	100
70. Delta	1,000	100	100
71. Delta	1,000	100	100
72. Delta	1,000	100	100
73. Delta	1,000	100	100
74. Delta	1,000	100	100
75. Delta	1,000	100	100
76. Delta	1,000	100	100
77. Delta	1,000	100	100
78. Delta	1,000	100	100
79. Delta	1,000	100	100
80. Delta	1,000	100	100
81. Delta	1,000	100	100
82. Delta	1,000	100	100
83. Delta	1,000	100	100
84. Delta	1,000	100	100
85. Delta	1,000	100	100
86. Delta	1,000	100	100
87. Delta	1,000	100	100
88. Delta	1,000	100	100
89. Delta	1,000	100	100
90. Delta	1,000	100	100
91. Delta	1,000	100	100
92. Delta	1,000	100	100
93. Delta	1,000	100	100
94. Delta	1,000	100	100
95. Delta	1,000	100	100
96. Delta	1,000	100	100
97. Delta	1,000	100	100
98. Delta	1,000	100	100
99. Delta	1,000	100	100
100. Delta	1,000	100	100

**APPENDIX A. (cont'd) ANALYSIS OF DOMESTIC SURVEILLANCE SAMPLES BY
COMMODITY GROUP IN 1993**

Commodity Group	Total No. of Samples	Samples with No Residues Found, %	Samples Violative, %	
			Over Tolerance	No Tolerance
Turnips	16	44	0	0
Other root/tuber vegetables	18	44	0	17
Vegetables, dried or paste	127	88	0	<1
Other vegetables/vegetable products	23	83	0	4
Total	2100	70	<1*	2
F. Other				
Peanuts	34	68	0	0
Other nuts & related products	19	89	0	0
Vegetable oil	19	95	0	0
Honey	28	96	0	0
Baby foods	16	100	0	0
Other food products	29	69	0	3
Total	145	83	0	<1
A-F Total	5703	64	<1*	1

* Includes samples that have both residue(s) over tolerance and residue(s) with no tolerance.

1994, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 26

**APPENDIX B. (cont'd) ANALYSIS OF IMPORT SURVEILLANCE SAMPLES BY
COMMODITY GROUP IN 1993**

Commodity Group	Total No. of Samples	Samples with No Residues Found, %	Samples Violative, %	
			Over Tolerance	No Tolerance
Mangoes	90	94	0	0
Papayas	113	80	0	10
Pineapples	144	74	3 ^a	<1
Plantains	30	93	0	0
Other tropical fruits	69	94	0	6
Cantaloupe	108	35	<1	0
Honeydew	68	22	0	0
Watermelon	52	73	0	4
Other vine fruits	21	62	0	10
Fruit jams & jellies	26	85	0	0
Fruit juices	61	89	0	0
Fruit toppings	23	96	0	0
Fruits, dried or paste	78	83	0	5
Other fruit products	9	78	0	0
Total	2261	61	<1^a	3
E. Vegetables				
Corn	30	97	0	0
Garbanzo beans/chick peas	13	77	0	0
Green/snow/sugar/sweet peas	105	63	0	13
Mung beans	11	82	0	0
String beans	67	51	1 ^a	10
Other beans, peas, & corn	51	69	2 ^a	2
Cucumbers	101	46	0	0
Eggplant	26	58	0	0
Okra	67	75	0	7
Peppers, hot	329	43	3 ^a	5
Peppers, sweet	199	74	<1	0
Pumpkins	18	89	0	0
Squash	155	49	<1 ^a	8
Tomatillos	22	41	0	0
Tomatoes	245	61	0	<1
Other fruits used as vegetables	38	79	0	5
Artichokes	45	87	0	4
Asparagus	146	82	3	1
Bamboo shoots	12	100	0	0
Broccoli	81	73	1	0
Broccoli raab	18	72	0	0
Brussels sprouts	13	69	0	0
Cabbage	34	79	0	3
Cauliflower	24	92	0	0
Celery	15	13	0	0
Chicory	32	100	0	0

TABLE 1. Continued

Variable	Mean	SD	Min	Max
Age	34.5	10.5	18	65
Gender				
Male	55.2			
Female	44.8			
Marital status				
Married	68.5			
Single	31.5			
Education				
High school	15.2			
Bachelor's	45.8			
Master's	38.5			
PhD	0.5			
Occupation				
Student	12.5			
Teacher	25.5			
Engineer	18.5			
Manager	35.5			
Other	8.0			
Income				
Low	15.5			
Medium	45.5			
High	39.0			

CHRONOLOGICAL OUTLINE OF FDA LEAD ACTIVITIES

- 1930 Initiated enforcement program on lead-based pesticides in fruits and vegetables.
- 1934-5 Developed new methods for the measurement of lead in food.
- 1962 Public Health Service set drinking water standard of 50 ppb lead (3/6/62).
- 1970 Surveyed leachable lead in imported ceramicware.
- 1971 Set action level of 7 ppm of lead from ceramicware to special leaching solution. Worked with industry on self-surveillance programs to limit lead migration.
- 1971+ Added silver-plated hollowware to existing CPG.
- 1971+ Set action level of 0.5 ppm leachable lead for silver-plated cups intended for use by infants.
- 1971 Ad Hoc Health, Education, and Welfare (HEW) Committee of Experts on Pediatric Lead establish guideline of 300 micrograms (mcg)/day as the maximum daily exposure to lead for children aged 1-3 years.
- 1973 Began analysis for lead in Total Diet Study.
- 1973 50 ppb limit of lead set for bottled water (11/26/73).
- 1977 Ad Hoc HEW Committee recommended total lead exposure not to exceed 100 mcg/day for infants under 6 months and 150 mcg/day for children 6 months to 2 years.
- 1978 FDA notice of guidelines on lead and cadmium in decorated glass tumblers.
- 1978 Lead acetate permanently listed as a color additive for hair dyes.
- 1979 Published plan to reduce lead content of canned foods by 50%.
- 1979 Infant juice and infant food manufacturers completed voluntary switch from lead soldered cans to glass jars.

- 1979 Published Memorandum of Understanding (MOU) with EPA and USDA for a study on background concentrations of cadmium, lead, and other selected metals in soils and crops in major production areas (44 CFR 44940).
- 1979 Action levels for lead in ceramic foodware (mcg lead per mL leaching solution) set for: flatware - 7; small hollowware - 5.0; large hollowware - 2.5 mcg lead.
- 1982 Joint EPA, FDA, and USDA Statement of Federal Policy and Guidance published on Land Application of Municipal Sewage Sludge for the Production of Fruits and Vegetables.
- 1982 Study finds lead in bone meal calcium supplements up to 12.8 ppm.
- 1985 Evaporated milk industry in U.S. completed conversion to non-lead soldered cans. FDA conducted evaporated milk survey.
- 1988 Congressional hearing on lead in housewares (6/27/88).
- 1988 MOU formalized with China (PRC) providing for certification by the Chinese Government that lead leaching from ceramicware is below the FDA action level.
- 1989 Published a proposal containing a provisional tolerable intake for food of 6-18 mcg/day for 10 kg child. Proposed a regulatory limit for ceramic pitchers of 0.1 mcg/mL (25 to 50 times lower than current action level).
- 1989 Investigation based on limited data showed that some coffee urns may release significant amounts of lead.
- 1991 Domestic can manufacturers cease production of food in lead soldered cans.
- 1991 FDA advised BATF that FDA could support enforcement action against wine containing more than 300 ppb. (September 9, 1991)
- 1991 Lowered the action levels for lead leaching from ceramicware (November 5, 1991). FR notice announcing revised levels and amended Compliance Policy Guide published July 6, 1992.

- 1992 Proposed rule to ban use of tin-coated lead foil capsules on wine bottles (11/25/92).
- 1993 As an interim measure to address some serious lead exposures from foods packed in lead-soldered cans until the ban on lead-soldered food containers can be finalized, FDA published a notice announcing emergency action levels for lead in food packed in lead-soldered cans (80 ppb for fruit beverages, and 250 ppb for all other foods). (April 1, 1993)
- 1993 Proposed rule to ban lead solder in all food cans (6/21/93).
- 1993 Published a notice providing an opportunity for comment on the revised Food Chemicals Codex policy to reduce the lead limits as well as the heavy metals limit to the lowest levels feasible for FCC substances. The Committee also solicited suggestions for lower limits for incorporation in food ingredient monographs.
- 1993 Issued a guidance document for lead in shellfish. (August, 1993)
- 1994 Published a final rule establishing requirements for decorative ceramicware to be deemed not for food use. (January 12, 1994)
- 1994 Published an Advance Notice of Proposed Rulemaking concerning reduction of the lead specifications for food additives, color additives, and GRAS (Generally Recognized As Safe) ingredients. (February 4, 1994)
- 1994 Published a final rule that reduced the allowable level for lead in the bottled water quality standard from 50 ppb to 5 ppb. (May 25, 1994)

ACTION LEVELS FOR LEAD IN PRODUCTS UNDER FDA JURISDICTION

LARGE HOLLOWWARE - 1 part per million

SMALL HOLLOWWARE - 2 parts per million

FLATWARE - 3 parts per million

CUPS/MUGS/PITCHERS - 0.5 parts per million

SILVER- PLATED HOLLOWWARE - 0.5 parts per million
(if article is intended for use by infants and children)

SILVER - PLATED HOLLOWWARE - 7 parts per million
(if article is intended for use by adults)

LIMITS FOR LEAD IN PRODUCTS UNDER FDA JURISDICTION

BOTTLED WATER - 5 parts per billion (final)

TIN-COATED LEAD FOIL CAPSULES ON WINE BOTTLES - prohibited
(proposed)

LEAD SOLDERED CANS - prohibited (proposed)

ENFORCEMENT CRITERION FOR LEAD IN OTHER PRODUCTS (1991)

WINE - 300 parts per billion



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

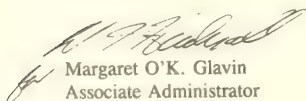
NOV 02 1994

Honorable Edolphus Towns, Chairman
House Subcommittee on Human Resources and Intergovernmental Operations
2232 Rayburn HOB
Washington, D.C. 20515-3210

Dear Mr. Chairman:

Enclosed herewith are the responses to your followup questions to the Hearing on Chemical Residues on September 28, 1994. If you have any questions or comments, please do not hesitate to call at (202) 720-3897.

Sincerely,



Margaret O.K. Glavin
Associate Administrator

Additional Questions for the Record

September 28, 1994, Hearing on USDA Residue Program
House Committee on Government Operations
Subcommittee on Human Resources and Intergovernmental Relations

REP. TOWNS

1. GAO found that the national residue program results that USDA has reported to the Congress were misleading for a variety of reasons. Do you agree with GAO and, if so, how do you plan to correct the reports in the future?

FSIS agrees that changes in reporting are necessary to prevent possible misinterpretation of residue results. Calculating violation rates across categories of slaughter classes with different sampling rates would require appropriate weighting of the sample results to be meaningful. Statistical inferences should not be made in reporting results of the National Residue Program (NRP) across species/compound class.

In order to avoid possible misinterpretation of testing results in the future, we have made changes to the 1993 Domestic Residue Data Book for the NRP. Explanatory notes have been added on pages i and ii of the 1993 Residue Data Book to better describe the NRP and its corresponding results. Page iii contains a cautionary note to advise readers on the proper interpretation of sample analyses and residue violations. A copy of these notes is attached. The 1994 Residue Data Book will include a statement explaining to readers that they should not combine data pertaining to violations between different slaughter classes.

2. Does USDA have a valid method to detect Alachlor and its metabolites in meat and poultry? If not, has USDA asked EPA to require the sponsor to provide a valid method? Please explain.

USDA has a method to detect Alachlor and its metabolites in beef and poultry liver. The method is adapted from a Monsanto method developed in the mid 1980s and has not been validated (e.g. it has not been successfully performed by three or more analysts at two or more locations). However, the method has been taught to and successfully performed by three analysts at a single FSIS laboratory. The Quality Systems Branch of the Chemistry Division, S&T Program, has certified that these analysts are capable of performing the Alachlor test method.

The major limitation to the FSIS method is the inability to successfully repeat it in a second laboratory. The method is not "rugged" in that successful results appear to be very dependent on the laboratory technique used by the analyst.

The method's sponsor, Monsanto, has provided EPA with a series of methods to detect Alachlor and its metabolites in field crops and meat and poultry over a number of years. To the best of our knowledge, none of these methods have ever been successfully repeated by Government laboratories following the written procedures provided to EPA by Monsanto as part of the pesticide registration process. The reason(s) for this are unclear, but speak to the harshness of the method's isolation step, which involves the use of a very caustic substance.

The Monsanto method FSIS has adapted can detect and confirm by mass spectrometry the presence of as little as 2 - 4 ppb of Alachlor or its individual metabolites. The EPA tolerance for Alachlor is 20 ppb for beef and poultry liver. FSIS is using the method to analyze samples taken in an on-going exploratory project to determine if Alachlor residues do, in fact, exist in various categories of livestock and poultry. Should this effort reveal that Alachlor residues are occurring, then FSIS can incorporate this or other methods for use as part of regular residue testing.

The problems associated with performing this Alachlor test method have been discussed regularly with both EPA and FDA/CFSAN at the quarterly meetings of the Tripartite Residue Methods Group (FDA, USDA, EPA). In response, Monsanto provided the above-mentioned series of method modifications to EPA. None of them have proved satisfactory for regulatory use. While waiting for Monsanto to submit a validated method to EPA for registration, FSIS proceeded with its modification of a Monsanto method developed in the mid 1980s and achieved the results described above.

On October 12, 1994, EPA announced that Alachlor is one of 85 pesticides the Agency will review over the next five years as part of its plan to phase out chemicals that violate the Delaney Clause. EPA has stated that it will examine Alachlor in its first round of reviews.

Has USDA routinely tested meat and poultry for TCDD and other dioxin compounds?

FSIS has not routinely tested meat and poultry for TCDD and other dioxin compounds because we do not presently have the laboratory capability needed to test routinely for these compounds. However, as a result of a Dioxin Reassessment Program being conducted by EPA, FSIS has implemented a limited dioxin residue

survey in cattle. The results of this survey will be available in November. The results of the review will clarify our options for a routine dioxin testing program.

REP. SANDERS

1. On the CBS Evening News last night, one farmer said that his cows got so sick from rBGH that he had to send many of them off to be slaughtered. It is my understanding that this is normal procedure for dairy cows that are no longer useful. What procedures are currently in place to protect the public from residues of synthetic BGH and other potentially risky substances related to the injections that are in the meat?

There are three analytical methods used to determine amounts of rBGH in treated animals. None of these can differentiate between synthetic and naturally occurring BGH. All three procedures were validated by their sponsors and extensively evaluated.

According to the Food and Drug Administration (FDA), the agency responsible for declaring rBGH safe and establishing tolerances for it, both BGH and rBGH have no biological activity in humans, even if injected. The human digestive system contains enzymes and acids that degrade these proteins, destroying the biological activity of both.

FSIS has a comprehensive screening program for antibiotic residues in the tissues of dairy cows presented for slaughter. Screening shows evidence of injection sites or other suspicious signs of medication. Carcasses showing violative residues during in-plant testing are withheld from production intended for human consumption.

2. Is it possible that we are eating beef that contains a synthetic hormone that makes cows so sick they are sent out for slaughter?

No. FDA has determined there is no evidence that rBGH poses a health threat to animals or humans. The compound has been studied more than any other animal drug and has been found to be safe for animals by FDA and other U.S. and foreign scientific bodies.

As part of the regulatory approval for veterinary drugs, FDA extensively evaluates the efficacy of the product as well as its animal and human health effects. Compounds that do not meet current FDA criteria are not approved for use in animals.

1993 DOMESTIC RESIDUE DATA BOOK

INTRODUCTION

The Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture (USDA) is responsible for ensuring that USDA-inspected meat and poultry products are safe, wholesome, free of adulterating residues, and accurately labeled. As part of this responsibility, FSIS conducts the National Residue Program (NRP) to help prevent the marketing of animals containing unacceptable (violative) residues from pesticides, animal drugs, or potentially hazardous chemicals. The NRP collects samples of meat and poultry products at domestic slaughter establishments under FSIS and State inspection authority. These samples are then analyzed for violative residue concentrations, either by one of the three FSIS technical service laboratories or by a laboratory under contract to FSIS. Violative residue concentrations - violations - are determined by reference to residue limits (tolerances or action levels) established for pesticides by the Environmental Protection Agency (EPA) and for animal drugs and environmental contaminants by the Food and Drug Administration (FDA).

The activities pursued by the NRP in 1993 were divided into two categories: monitoring and individual enforcement testing.

Monitoring

Monitoring is designed to provide information on the occurrence of residue violations in specified animal populations on an annual, national basis. Because the primary concern of monitoring is violations, generally compounds with established limits - tolerances or action levels - are considered. Residue limits pertinent to the 1993 NRP are listed in Appendix I. In some cases compounds without established limits will be included in monitoring; only those compounds that are a public health concern and are not legally approved for any use in food animals would be included. Selection for monitoring is based on compound evaluations and the availability of laboratory methodology that is suitable for regulatory purposes. ~~It should also be borne in mind that multi-residue tests may detect some compounds that have tolerances but have little public health significance.~~ See FSIS publication Compound Evaluation and Analytical Capability/National Residue Program Plan [CEAC/NRPP], 1993 edition.

Monitoring information is obtained through a statistically-based selection of random samples from healthy-appearing animals under inspection. ~~Monitoring is not designed to estimate the actual percentage of violations in the national population.~~ Rather, the number of samples chosen in the annual plan for a given compound-species combination is intended to detect a national problem that affects a specified percentage of the animal population of interest. The sample sizes that are most often used provide a 95 percent probability of detecting at least one violation when one percent of the animal population

1993 DOMESTIC RESIDUE DATA BOOK

Confirmed STOP positive sample specimens with sulfonamide residues that have no established limits are considered violative in those slaughter classes in which they are not approved for use.

FAST, for Fast Antimicrobial Screen Test, quickly detects both antibiotic and sulfonamide drug residues in kidneys and livers and has proved to be a suitable replacement for CAST and STOP. FAST was implemented in pilot plants in 1993.

Sample Analyses/Violations

The reader reviewing the 1993 Residue Data Book is cautioned against equating total residue violations with total sample units that are violative. For example, tissue from one animal analyzed by the Chlorinated Hydrocarbons and Organophosphates screening method may contain two or more violative residues.

It should also be noted that many sample tissues are analyzed for more than one compound or compound class and are reported here as separate analyses or violations. Each will be reported and included in total residue findings, even though occurring in the same animal.

In this format, the main entries under compound or compound-class headings refer to sample analyses; the "Specific Violative Residues" presented in smaller type refer to the actual residues found. In addition, analytical capabilities should be considered when interpreting residue levels and occurrences; see the 1993 edition of the CEAC/NRPP, Section 3, "FSIS Residue Analytical Capability."

A Note on Calf Nomenclature

This edition follows the usage of the 1989 and later editions of the CEAC/NRPP. What was called "Fancy calves" in the 1988 edition became "Formula-fed calves" in 1989; what was called "Western calves" in 1988 became "Heavy calves" in 1989.

Non-Violative Positive Results

Appendix II displays, for monitoring and individual enforcement testing (excluding CAST), those laboratory-confirmed residues that are within established limits. The results include some Unidentified Microbial Inhibitors (UMI's), residues from antibacterial agents that cannot be accurately identified but are nevertheless present.

Voluntary Inspection Program

A voluntary inspection and certification program is maintained for rabbits; results from 1993 are presented here in Appendix III.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 28 1994

Food and Drug Administration
Rockville MD 20857

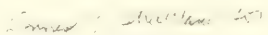
The Honorable Edolphus Towns
Chairman, Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Chairman:

This is in response to your letter of October 6, 1994, containing additional questions from you and from Representative Sanders for the record of the September 28 hearing regarding Federal food safety programs. We regret the delay in providing you with our enclosed answers.

If you have any questions, please do not hesitate to contact Carolyn Hommel on my staff, at 301/443-3793.

Sincerely,


Diane E. Thompson
Associate Commissioner
for Legislative Affairs

Enclosure

cc: The Honorable Steven Schiff
Ranking Minority Member

Questions from Representative Sanders:

Question 1: Earlier I mentioned the increased potential for antibiotics in milk produced with rBGH that you termed a "manageable risk." I want to be sure the risk is being managed. Further, in 1992, the GAO found that your milk monitoring process was inadequate. Do you monitor all of the antibiotics that veterinarians use to treat the cow health problems caused by rBGH (including aminoglycosides such as gentamicin)?

Answer:

- Although FDA cannot test every milk sample for every antibiotic used to treat cow health problems, FDA's National Drug Residue Milk Monitoring Program (NDRMMP) does test routinely for the most commonly used antibiotic drugs: eight sulfonamides, three tetracyclines, chloramphenicol, and beta lactam antibiotics. (Based on information in a commercial animal drug use database, FDA animal drug experience reports, and our surveillance of veterinary drug use patterns, about 89% of all mastitis is treated with beta lactam antibiotics. About 4% is treated with macrolide antibiotics such as erythromycin, 2% with tetracycline type antibiotics, and about 5% of mastitis is treated with other types of antibiotics.) The NDRMMP also tests milk for clorsulon, novobiocin, ivermectin, and gentamicin.
- Since 1992, the dairy industry has been required to assay each tank truck for beta lactam antibiotics and in July 1992, the States began monitoring the assay work of the industry. Producers must have a permit which can be suspended or withdrawn for sale of milk with violative drug residues. In addition, the fines for violative residues are severe and provide a powerful incentive for milk producers to prevent violations.
- In January 1994, the milk program was updated to add analyses performed by certified State laboratories using "quick screening" test kits that were provided by FDA. This results in many more samples being analyzed than was possible before the kits were available. In the first half of 1994, States reported running a total of 2,520 tests for beta lactam drugs, chloramphenicol, sulfonamides, tetracycline, and gentamicin. None of these samples contained violative residues following confirmatory analyses.

Question 2: If not, you're not managing the risk of increased antibiotics, so why did you approve the use of rBGH?

Answer:

Posilac® was approved because FDA found it to be a safe and effective production drug.

Question 3: I'm confused why the manageable risk standard was used anyway considering we have a surplus of milk and rBST does not offer any benefit to society. Therefore, if you had done a risk/benefit analysis of rBGH it would not have been approved. Is a risk/benefit analysis a requirement to approving production drugs like rBGH?

Question 4: If not, why not?

Answer:

No. The Federal Food, Drug, and Cosmetic Act does not authorize FDA to consider the general social or economic benefits to society (or lack thereof) when approving a new animal drug.

The Act requires FDA to determine whether new animal drugs are safe and effective under the conditions of use proposed by the manufacturer. Under the Act, the effectiveness determination requires "substantial evidence" that a drug "will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." The Act does not require that the claimed effect represent a benefit to the animal to which the drug is administered, thereby permitting the approval of drugs which are intended to enhance food production (production drugs) rather than benefit the animal in any medical sense.

FDA traditionally has demanded, as a condition of approval, that production drugs be shown to produce a significant positive biological effect. Typically, this effect is described in labeling in terms of improved feed efficiency, enhanced growth, or enhanced production of milk, eggs, or progeny. This proof constitutes a substantial burden on drug sponsors, in terms of time, effort, and money. If any question remains regarding whether a claimed production enhancing effect is real, FDA will not approve the drug. The scientific standard applied by FDA is extremely rigorous. Moreover, if the proposed use of a production drug presents risks to the target animal which result in decreased production, then those production losses would have to be factored into FDA's effectiveness determination, in addition to the risks being assessed from the standpoint of target animal safety.

FDA has never interpreted the Act's new animal drug safety provisions as requiring a demonstration that a drug present absolutely no risk. The Act requires a demonstration of safety by "all methods reasonably applicable," and directs FDA to take into account the probable consumption of the drug and any

substance formed in or on food as a result of the drug, the cumulative effect on man or other animals, whether the conditions of use are likely to be followed, and permits consideration of "safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data." If the drug is proposed for use in food-producing animals, then the safety assessment encompasses both an animal and human component.

During the new animal drug approval review process, FDA thoroughly characterizes the risks to the target animal associated with the use of a particular product. FDA traditionally has assumed that all animal drugs, if used widely, will be shown to have some adverse effects on some treated animals. Thus, even if no adverse effects are observed in the target animal at the use level being tested in the extensive battery of target animal safety studies that FDA requires, we do not assume the product is risk-free: the Agency assumes that no risk sufficient to deny approval has been detected. In other words, the target animal safety trials indicate that the risk associated with the use of the drug is insignificant and therefore acceptable.

Question 5: If a risk/benefit analysis was used:

- a. Why did you conclude that rBGH passed this test?
- b. What was the benefit?
- c. Were the benefits only economical?
- d. Is FDA supposed to consider economics when approving a production drug?
- e. The OMB estimated that rBGH would cost the government \$500 million over 5 years and would reduce farm income by \$1.3 billion dollars over the same time period. Did you consider these economic costs when doing the risk benefit analysis?

Answer:

FDA does not consider any socio-economic "benefits" of an animal drug when deciding whether that drug is safe because the language of the Act does not authorize or require consideration of such benefits in determining its safety.

Question 6: How do you define "manageable risk"?

Answer:

A manageable risk is one that is well-understood and readily dealt with by the user.

The Act provides that FDA can take steps to decrease all known and potential risks of an animal drug by restricting its use or requiring that its labeling acknowledge and describe the risk. Thus, when FDA determines that a risk can be decreased by acknowledging it in the drug's labeling and, if necessary, including additional information about addressing the risk, FDA requires the information in the labeling. (In addition to indications for use and directions, drug labeling typically contains information relating to contraindications, warnings, and side effects.)

Question 7: In fact, isn't it true that the "manageable risk" standard that was used in the approval of rBGH was used for the first time in the approval of rBGH?

Answer:

No.

While the phrase "manageable risk" may not have been routinely used, the approval process described in the answer to Questions 3 and 4 traditionally has been applied to all new animal drugs, including those intended for production enhancement, approved by FDA. The approval of Posilac® is consistent with this history.

Question 8: Why was this new standard adopted for this application?

Answer:

See previous answer.

Questions from Chairman Towns:

Question 1a: What is FDA's timetable for issuing final HACCP regulations for seafood and for issuing proposed HACCP regulations for other food products?

Answer:

FDA's proposed timetable is as follows:

- Proposed HACCP regulations for seafood: published in January 1994. Final regulations are expected to publish in 1995.
- Advance Notice of Proposed Rulemaking (ANPR) regarding HACCP requirements for all foods: published in August 1994; comment period closes December 2, 1994.
- Voluntary HACCP pilot programs will run through 1995.

Question 1b: To what extent are chemical residues and contaminants addressed in these regulations?

Answer:

FDA has proposed that HACCP programs cover all risks, whether microbiological, chemical, or physical. A final determination will be made after all comments on the proposed regulations have been received and evaluated.

Question 2a: How do you plan to ensure that imported products, especially non-seafood products, comply with HACCP requirements?

Answer:

FDA has not yet resolved this issue and has requested comments as part of the notice and comment rulemaking process for the Proposed Rule for HACCP programs for seafood (published in January 1994) and the Advance Notice of Proposed Rulemaking for HACCP programs for all other foods (published in August 1994).

For example, in the Proposed Rule for HACCP programs for seafood and seafood products, FDA proposed that imports be subject to the general HACCP provisions which require products that are offered for import to be produced under the same HACCP and sanitation controls that FDA is proposing to apply to domestically produced seafood. Furthermore, FDA is proposing to require that importers have an HACCP plan that includes the criteria for how they will decide to purchase and handle seafood while it is under their control, and establish ways to determine that these requirements are met. Importers also would be required to have on file a HACCP plan from each of their foreign suppliers and processors, who would be required to maintain appropriate records as dictated by HACCP principles.

In the Advance Notice of Proposed Rulemaking regarding the development of HACCP programs for all foods, FDA has also requested comments on efforts to harmonize HACCP standards with those of other countries and the role that Codex Alimentarius should play.

FDA will review and evaluate the comments submitted under these proposals, and publish the Agency's determination in future notices.

Question 2b: Should the Congress consider requiring that all high-risk food products eligible for export to the United States --not just meat and poultry--be produced under equivalent food safety standards?

Answer:

The Administration supports implementation of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT). Implementation of GATT would require an exporting country to demonstrate objectively that the health measures it applies afford a level of health protection equivalent to that afforded by the importing country's health measures. Furthermore, U.S. legislation already requires that imported products be as safe as domestically produced products.

Question 3: What are FDA's limits for methylmercury in seafood products and are these limits enforceable?

Answer:

- FDA has an action level of 1 part per million (ppm) methylmercury in swordfish, tuna, and shark.
- Action levels do not have the force of law, but they do provide guidance to FDA's field offices as to when a product is likely to be adulterated, and represent the levels at which FDA is prepared to take enforcement action.

Question 4: GAO concluded that even if FDA implements HACCP, the agency will still lack adequate enforcement tools. Do you agree with GAO and, if so, specifically what additional enforcement tools does FDA need?

Answer:

The Administration's pesticide food safety reform proposal (introduced as H.R. 4362 and H.R. 4329 during the 103rd Congress) contains provisions to strengthen FDA's enforcement authorities with respect to foods that contain illegal pesticide residues, such as the ability to levy civil money penalties, require recalls, and embargo food.

Question 5: To what extent, if any, is FDA's total diet study statistically representative of chemical residues and contaminants in the Nation's food supply?

Answer:

FDA's Total Diet Study is not designed to provide "statistically representative" data on pesticides, chemical contaminants or nutrients in the U.S. food supply in any particular year. The cost required to do so would be prohibitive and would exceed several times over the entire amount of resources FDA expends currently for enforcement programs to monitor pesticides and chemical contaminants in foods.

Nevertheless, FDA believes that the Total Diet Study data, which have been collected since 1961, provide a reliable picture of the nature and scope of the risks from pesticides and chemical contaminants in the U.S. food supply. If resources become available to expand the Total Diet Study, it is likely that FDA would elect to include additional subpopulations in the current study, rather than pursue a "statistically representative" study, per se.

Question 6: Why didn't FDA compare its surveillance residue data with USDA's pesticide data program before FDA started its own pilot program to collect statistically based residue data? [See Food Safety: Changes Needed to Minimize Unsafe Chemicals in Food (GAO/RCED-94-192, September 26, 1994, p. 25)] What are FDA's plans regarding this pilot program or other efforts to collect statistically based residue data?

Answer:

- FDA has been directly and deeply involved in all aspects of USDA's Pesticide Data Program (PDP) from inception in 1990 to the present. FDA technical and policy staff have reviewed data and draft reports on findings from the PDP on many occasions since that time. As FDA pointed out to GAO in the Agency's review of its recent report (GAO/RCED-94-192), we believe GAO is incorrect in its assessment that FDA did not compare its surveillance data with PDP data prior to initiating FDA's statistically based pesticide residue surveillance program. FDA initiated its statistically based programs in July 1992 after several years of careful planning and with full awareness of the differences between its program and the PDP, as well as the findings of the PDP.
- Because of insufficient resources, FDA will discontinue its statistically based pesticide residue surveillance program when the current studies for apples and rice are completed in December 1994.

Question 7: Has FDA established tolerances, action levels or guidelines for dioxin compounds in food products and, if so, what are they? If FDA has not, why?

Answer:

- FDA has not established formal tolerances for dioxins in foods because the risks posed by dioxin in products within FDA's jurisdiction are not sufficient to divert the resources that would be necessary to establish formal tolerances. If, in the future, FDA determines that formal tolerances are needed to protect the public health, the Agency will take all necessary actions to establish them.
- FDA has worked successfully with the paper industry to reduce voluntarily the levels of dioxin and furans in food contact paper products. Changes to chlorine bleaching procedures and other processes have reduced dioxin and furan levels from approximately 10 parts per trillion (ppt) to less than 2 ppt.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 2 1994

OFFICE OF CONGRESSIONAL
AND LEGISLATIVE AFFAIRS

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources and
Intergovernmental Relations
Committee on Government Operations
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Enclosed are EPA's responses to the questions contained in your letter of October 6, 1994 following up on the September 28, 1994 hearing on chemical residues and contaminants in food.

If we can be of further assistance, please have your staff contact Ken Wood on 202-260-5429.

Sincerely,

A handwritten signature in dark ink, appearing to read "Christopher P. Hoff".

Christopher P. Hoff
Deputy Director
Legislative Analysis Division

Question 1: In a recent article of the Washington Post Colman McCarthy quoted EPA as saying, "Because EPA has determined that the body burdens of dioxin are at or near the level associated with adverse health effects--cancer, reproductive, developmental and immune suppression-- there is need for government intervention." Is this statement correct? If yes, please provide the written source for this quote.

Answer: Yes. EPA has taken the position that, because the margin of exposure between average body burdens and levels expected to be associated with adverse non-cancer impacts is not as large as previously thought and because EPA has reconfirmed the potential cancer risk to human populations, ongoing government action particularly to reduce releases of dioxin and related compounds to the environment is warranted. While the science of the reassessment is undergoing peer review, EPA will be examining the reassessment's policy implications to determine what changes, if any, are needed in its existing programs. EPA is committed to developing and completing an Agency-wide strategy for managing dioxin risks, concurrent with completion of the dioxin reassessment. However, existing EPA efforts and programs will not be changed on the basis of the draft reassessment without the completion of the peer review. We are not aware of any written source for the Washington Post quote.

Question 2: In Dr. Goldman's prepared statement she stated that "...the benefits of a balanced diet, including increased consumption of fresh fruits and vegetables, far outweigh any theoretical risks from dioxin exposure. Following Federal guidelines to reduce intakes of fat, especially saturated fats, will decrease dioxin consumption but much more effective are measures to reduce dioxin emissions."

- If EPA has determined that human body burdens are already at or near the level associated with adverse effects, how is the risk theoretical?
- Has EPA done a risk assessment to determine whether following Federal dietary guidelines will sufficiently protect people, especially vulnerable subpopulation groups, against adverse effects of dioxin? If yes, please provide a copy of this risk assessment to the subcommittee. If no, why?

Answer: EPA has determined that human body burdens are at or near comparable levels which produce adverse effects in laboratory animals. It has also provided support for the belief that some humans may respond at similar levels. Subtle changes in biochemistry and physiology such as enzyme induction, altered levels of circulating reproductive hormones, or reduced glucose tolerance, have been detected in TCDD-exposed men in a limited number of available studies. These findings, coupled with knowledge derived from animal experiments, suggest the potential for adverse impacts on human metabolism, and developmental and/or reproductive biology, and, perhaps, other effects in the range of current human exposures. It is not currently possible to state exactly how or at what levels humans in the population will respond but the margin of exposure (M-O-E) between background levels and levels where effects are detectable in humans is considerably smaller than previously estimated. Despite this potential for adverse non-cancer effects, there is currently no clear indication of increased disease in the general population attributable to dioxin-like compounds. It is in this context that the risks are considered "theoretical." The lack of a clear indication of disease in the general population should not be considered strong evidence for no effect of exposure to dioxin-like compounds. Rather, lack of a clear indication of disease may be a result of the inability of our current data and scientific tools to directly detect effects at these levels of human exposure.

No risk assessment has been done to specifically determine whether following Federal dietary guidelines will sufficiently protect people against the adverse effects of dioxin. The determination of whether people are "sufficiently" protected is a risk management decision. It stands to reason, however, that the well established benefits of a

healthy diet that limits the intake of fats will have the added benefit of reducing intake of dioxin compounds which, because of their chemical nature, are accumulated in animal fats. The risks of exposure to dioxin-like compounds at average exposure levels are far less certain and, to the best of our current knowledge, any impacts considered detrimental to health would be far outweighed by the known, positive impacts of a varied, healthy diet.

Question 3: How many cases of cancer are caused by dioxin compounds annually in the United States? How many cases of cancer are caused by dietary exposure to dioxin compounds annually in the United States?

Answer: Since dioxin and related compounds are considered to be "probable" human carcinogens, and are not "known" to be carcinogenic, it is possible that no cancers may be attributable to dioxin and related compounds. However, if we assume that dioxins represent a carcinogenic hazard to humans and assume that average daily intakes correlate with cancer risk, the EPA estimates that, at most, 1,000-2,000 cancer cases a year may be attributable to exposure. The "true" number cannot be determined but is likely to be less and, as stated above, may even be zero. Since the EPA has adopted the hypothesis that humans are exposed to minute quantities of dioxin-like compounds primarily through the food pathway, dietary exposures would also account for the vast majority of the theoretical risk. EPA will continue to evaluate cancer incidence due to dioxin exposure during the reassessment/peer review process.



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

SEP 26 1994

Honorable Edolphus Towns
Chairman
Subcommittee on Human Resources
and Intergovernmental Relations
Committee on Government Operations
U.S. House of Representatives
B-372 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Chairman:

This letter is in reply to a request made by Mr. Bill Layden, of your staff, in a briefing held with representatives of the Food Safety and Inspection Service on Tuesday, September 20, 1994.

At the briefing, Mr. Layden asked for a written explanation of the violation rate for heavy metals in Australia's and New Zealand's residue monitoring programs. Our response and the documentation that supports it follows.

Regarding Australia heavy metal data, the Australian National Residue Survey Summary Report was the result of a computational error. There was, in fact, not a violation of U.S. residue standards. The Food Safety and Inspection Service explained the errant Australian data to the GAO investigator during interviews with International Programs personnel. Dr. Jack Haslam, of the Australian Embassy, submitted correspondence dated February 10, 1994, that explained the cause and the corrective action taken in Australia's 1993 Residue Summary Report. This correspondence is enclosed.

Regarding New Zealand heavy metal data, the violations are based on the New Zealand standards. There was not a violation of U.S. residue standards. Nevertheless, any product found to be in violation of the New Zealand standard would be condemned by New Zealand and therefore, would not be exported into the United States. Most violations are found in equine and ovine.

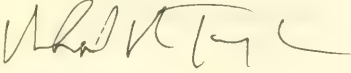
Honorable Edolphus Towns

2

Regarding residue violations detected in samples collected at import inspection: 1990--14,170 samples tested--11 violations; 1991--18,479 samples tested--7 violations; 1992--16,113 samples tested--8 violations; 1993--16,069 samples tested--8 violations, and 1994, January 1 to August 3--12,268 samples tested--1 violation. A listing of the violations by country and type of residue is attached for your information.

Please contact me if you have any further questions.

Sincerely,

A handwritten signature in dark ink, appearing to read "Michael R. Taylor", with a stylized flourish at the end.

Michael R. Taylor
Administrator

Enclosures

10 February 1994

Mr Jack Hadam
 Counsellor, Veterinary Services
 Australian Embassy
 1601 Massachusetts Ave, NW
 WASHINGTON DC 20036 USA

SUMMARY NRS DATA SENT TO THE USDA

Your facsimiles, reference 206/9/2, dated 4 February and 8 February refer.

With regards to the GAO query on the NRS (1992?) results for zinc in beef liver

- the MPC of 0.500 mg/kg is an error in the report due to our misinterpretation of the entry for 'zinc ion and maneb (mancozeb)' in the 'Hins Book'.
- mancozeb is a dithiocarbamate and is not included in the NRS meat program.
- the heavy metal test performed for the NRS includes the analysis of total zinc.
- the USA has no MPCs (tolerances) for any heavy metal other than arsenic in pigs and poultry.

The entry for the number of samples tested for heavy metals can be interpreted

- 1293 samples were analysed for a number of heavy metals
- 4544 residues were detected in 1293 samples
 - one sample can have residues of more than one chemical
- (about) 1900 samples contain residues of zinc. (I cannot replicate precisely the report that was sent to USDA as additional data for that year has been entered into the database since the report was produced.)



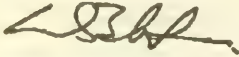
Director: John Curtis House 22 Brisbane Avenue Barton ACT 2600
 post: PO Box 871 Queen Victoria Terrace Perth ACT Australia 2600
 Phone (06) 272 6282 Fax (06) 272 6767

B R S

THE USA MRL FOR ZINC HAS BEEN AMENDED IN OUR DATABASE PRIOR TO THE PREPARATION OF THE 1993 RESULTS WHICH WERE FORWARDED TO THE USDA IN JANUARY 1994. THE ENTRY READS "***** NO LIMIT SET"

ATTACHED IS AN EXTRACT FROM THE 'AUSTRALIAN FOOD STANDARDS CODE 1992' WHICH LISTS THE LIMITS FOR METALS AND CONTAMINANTS IN FOOD, AS REQUESTED.

I HOPE THIS ANSWERS YOUR QUERY.



NORM BLACKMAN
Manager
Food Safety Assessment Section

STANDARD A12
METALS AND CONTAMINANTS IN FOOD

(1) For the purposes of this Standard and save where the contrary intention appears -

- (a) 'metal' includes compounds of a metal;
- (b) where food contains a metal and any compound or compounds of that metal, that metal and compound or compounds shall be expressed as the metal;
- (c) antimony, arsenic and selenium are deemed to be metals;
- (d) maximum permitted concentration shall be determined on the edible portion of the food that is ordinarily consumed and, in the case of food in a dried, dehydrated or concentrated form, shall be calculated with respect to the mass of the food after dilution or reconstitution;
- (da) maximum permitted concentration for seaweed (edible kelp) whether dried, dehydrated, concentrated or not shall be calculated with respect to the mass of the seaweed as 83% hydrator and
- (e) 'beverages and other liquid foods' include fruit juices and beverages with a fruit juice content, milk, alcoholic beverages and frozen liquid foods, but do not include thick gels or other semi-solid foods.

(2) Subject to clause (2A), food specified in column 2 of the Table below shall not contain a metal specified in column 1 thereof in a concentration greater than the maximum permitted concentration specified opposite and in relation to that food in column 3 thereof.

(2A) A maximum permitted concentration of a metal specified in the Table in clause (2) does not apply to carbonated water, soda water or mineralised water, or to mineral water, if a maximum concentration of that metal is specified in Standard O13 or Standard O8 in relation to that food.

TABLE

Column 1 Metal	Column 2 Food	Column 3 Maximum permitted concentration in food (mg/kg calculated as the metal)
Antimony	Beverages and other liquid foods	0.15
	All other foods	1.5
Arsenic	Beverages and other liquid foods	0.1
	Quillies (chicken) livers	2.0
	Fish, crustaceans and molluscs (inorganic arsenic only)	1.0
	Seaweed (edible kelp) (inorganic arsenic only)	1.0
	Wheat	0.05
	All other foods	1.0

June 1993

Cadmium	Beverages and other liquid foods	0.05
	Brin	0.2
	Crustaceans and the crustacean content of products containing crustaceans	0.2
	Fish and fish content of products containing fish	0.2
	Edible offal other than liver	2.5
	Liver	1.25
	Meat muscles	0.2
	Molluscs and the mollusc content of products containing molluscs	2.0
	Seaweed (edible help)	0.2
	Water	0.005
	Wheat germ	0.2
	All other foods	0.05
Copper	Beverages and other liquid foods	5.0
	Cocoa and chocolates	50.0
	Edible offal other than ovine livers	100.0
	Ovine livers	200.0
	Molluscs and the mollusc content of products containing molluscs	70.0
	Water	1.0
	All other foods	10.0
Lead	Beverages and other liquid foods	0.2
	Brin	2.5
	Fish in tinplate containers	2.5
	Fruit juices and fruit juice drinks	0.5
	Infants' foods in containers other than tinplate	0.3
	Infants' foods in tinplate containers	A mean level of 0.3 is 10 sample units. No sample unit shall exceed 0.3.
	Meat in tinplate containers	
	Milk, condensed milk and liquid milk products in tinplate containers	
	Molluscs	
	Tomato products, as specified in Standard F2, in tinplate containers	2.5
	Vegetables	2.0
	Water	0.05
	Wheat germ	2.5
	All other foods	1.5
Mercury	Fish, crustaceans, molluscs and the fish content of products containing fish	A mean level of 0.5 ^a
	Water	0.001
	All other foods	0.03
Selenium	Beverages and other liquid foods	0.2
	Edible offal	2.0
	Water	0.01
	All other foods	1.0

Tin	Foods not packed in direct contact with tin	30.0
	Any of the following canned foods in direct contact with tin:	
	Asparagus	250.0
	Fruits	250.0
	Fruit juices	250.0
	Green beans	250.0
	Tomato products as specified in Standard P2	250.0
	Foods packed in tins containing medium	200.0
	All other foods	150.0
Zinc	Beverages and other liquid foods	5.0
	Oysters	1000.0
	Water	5.0
	All other foods	150.0

* The mean level of mercury in fish, crustaceans, molluscs and the fish content of products containing fish in the prescribed number of sample units, as determined by the methods prescribed by clause (7) of this Standard.

(3) (a) The proportion of vinyl chloride monomer in any food shall not be greater than 0.05 mg/kg.

(b) The proportion of acrylonitrile monomer in any food shall not be greater than 0.02 mg/kg.

(c) The proportion of vinylidene chloride monomer in any food shall not be greater than 0.01 mg/kg.

(4) The proportion of aflatoxins in food shall not be greater than -

- (a) in peanut butter or peanut paste, nuts and the nut portion of products containing nuts, 15 µg/kg;
- (b) in all other foods, 5 µg/kg.

(4A) The proportion of phorbolins in any food shall not be greater than 5 µg/kg.

(5) Ergot shall not be detectable in a 2.25 litre sample of cereal grain.

(6) The proportion of polychlorinated biphenyls shall not be greater than -

- (a) in fat of meat, fat of meat of poultry, milk, milk products and eggs, 0.2 mg/kg;
- (b) in fish, 0.5 mg/kg.

(7) Methods of sampling and analysis. The methods specified in this clause are the prescribed methods for the sampling for analysis of mercury in fish and fish products.

(a) Preliminary.

(i) For the purposes of this sampling plan, a sample shall consist of a prescribed number of sample units, and a sample unit shall consist of a quantity, taken from the edible portions of fish including sharks, rays and scale fish, crustaceans or molluscs, sufficient for the purposes of analysis.

June 1992

01/93 National Residue Survey Page 2
 SUMMARY REPORT For Sample Dates From 01/01/92 Until 31/12/92
 MEAT SAMPLER RESULTS Note: (DDT Total) listed but not included in totals.
 ALL STATES USA Maximum Residue Limits

	Total SAMPLES	Tot with RESID'S	Total RESID'S	Total %VIOL VIOL. of TOTAL	MRL/MPC mg/kg
BEEF KIDNEY					
CYROMAZINE	179	0	0		
BEEF LIVER					
AVERMECTIN/IVERMECTIN	601	9	9		
***** avermectin			0		
ivermectin			9	3	0.50% 0.015
***** No MRL has been set					
BENZIMIDAZOLES	235	0	0		
LEVAMISOLR	284	0	0		
levamisole			0		
METALS	1293	1292	4544		
***** mercury			65		
zinc			1292	1290	99.80% 0.500
***** copper			1289		
***** cadmium			831		
***** lead			53		
***** arsenic			18		
***** selenium			996		
***** No MRL has been set					
ZERANOL & STILBENES					
zeranol	685	3	5		
talernanol			3	1	0.10% 0.030
			2		
SULPHONAMIDES	1717	0	0		
TRENBOLONE	204	0	0		
trenbolone			0		
TRICLABENDAZOLE	278	0	0		
BEEF MUSCLE					
CHLORAMPHENICOL	272	0	0		
BEEF Serum (from whole blood)					
NITROFURANS (furazolidone)	241	0	0		
***** furazolidone			0		
***** No MRL has been set					

FOOD SAFETY AND INSPECTION SERVICE

IMPORT RESIDUE VIOLATIONS

1990 - 1994

1990 - 11 Violations		
COUNTRY	NUMBER OF VIOLATIONS*	RESIDUE
Italy	3	Sulfonamide
Switzerland	2	Sulfonamide
Canada	4	3 Sulfonamide 1 Antibiotic

* Two laboratory reports missing from the file.

1991 - 7 Violations		
COUNTRY	NUMBER OF VIOLATIONS	RESIDUE
Italy	2	Sulfonamide
Switzerland	1	Sulfonamide
Netherlands	2	Sulfonamide
Canada	1	Sulfonamide
Poland	1	Sulfonamide

FOOD SAFETY AND INSPECTION SERVICE

IMPORT RESIDUE VIOLATIONS

1990 - 1994

1992 - 8 Violations		
COUNTRY	NUMBER OF VIOLATIONS	RESIDUE
Australia	1	Cypermethrin
Mexico	1	Sulfonamide
New Zealand	1	Sulfonamide
Canada	4	Sulfonamide
Belgium	1	Sulfonamide

1993 - 8 Violations		
COUNTRY	NUMBER OF VIOLATIONS	RESIDUE
Belgium	1	Sulfonamide
New Zealand	2	1 Sulfonamide 1 Chlorfenvinphos
Australia	5	Chlorfenvinphos

1994 - 1 Violation as of August 3		
COUNTRY	NUMBER OF VIOLATIONS	RESIDUE
Israel	1	Sulfonamide

Food & Drink Daily

Volume 4, Number 860 FD

Friday, September 30, 1994

Call For Single Food Agency Grows Louder *Lawmakers, Backed By GAO, Assail Oversight Of Residues In Food*

By John Donnelly

Members of a congressional subcommittee looking into the problem of chemical residues and other contaminants in the food supply said Wednesday that the federal government had better get its act together—literally.

The government's act is fragmented among three agencies, the congressmen said. They renewed calls to consolidate food safety regulation in a single, brand-new public-health agency.

Armed with a pair of General Accounting Office (GAO) report cards giving the government poor marks for its efforts to combat these problems, the members of a House Government Operations subcommittee scolded the nation's top food safety officials for their inferior grades.

Essentially, the officials' response was: the dog ate my Hazard Analysis Critical Control Points proposal.

The Human Resources and Intergovernmental Relations Subcommittee hearing was the fourth in a series reviewing Vice President Al Gore's recommendations for "reinventing" the food safety system by consolidating government programs.

What began in this subcommittee as a suggestion has become a vociferous demand that the government put these efforts under one roof.

"The more I have studied this, the more I'm convinced of the need to centralize food safety inspection into

one agency," said the subcommittee chairman, Rep. Edolphus Towns.

The New York Democrat said he will formally ask the GAO to report to him on the best way to effect the consolidation.

The subcommittee's ranking minority member, Rep. Steven Schiff, R-N.M., agreed: "We have representatives testifying from three different government agencies with responsibility in this area.... That's an inherent problem."

Schiff said conflicting mandates—promoting meat and poultry in the marketplace and insuring the products' safety—place USDA in "an eternal tug of war."

Each of the three agencies which regulate the food supply sent comments to the GAO on a draft of the report. USDA generally concurred with the recommendation of a single

food agency. The Food and Drug Administration said the report was outdated and that its data did not support its conclusions.

The Environmental Protection Agency suggested that an interagency council would be a better idea. The GAO said that would not solve the underlying legal patchwork.

Past interagency taskforces have "either lapsed into inaction because of a lack of commitment or resources by the agencies involved or just became forums to facilitate the exchange of information between agencies. Interagency groups worked effectively only when they were established to respond to urgent and life-threatening situations," the GAO said.

The lack of a single, coherent bureaucracy responsible for food safety was the GAO's—and the congress-

(Continued on page 2)

Heinz To Take Over Glaxo India Unit For \$67 Million

NEW DELHI—Heinz Co. will sign a nearly \$67 million deal next Monday to take over Glaxo Laboratories (India) Ltd.'s food products division, Heinz's chief executive A.F.J. O'Reilly said Thursday.

"We are happy to have arrived in India through acquisition of the food products division of Glaxo," O'Reilly said.

The plant in the north Indian city of Alligarh employs 1,000 people, he said, and Heinz expects to add new employees and brands.

Glaxo Laboratories is a unit of Glaxo Holdings Plc of London, a pharmaceuticals giant.

GAO: Federal Monitoring Of Residues Is Fragmented... (From page 1)

men's—fundamental criticism, but not the only one.

Towns said he had asked the GAO to explain how the government is doing in ensuring the food supply does not contain unsafe chemical residues and other contaminants.

"The answer is frightening," Towns said in his opening statement. He called the approach of USDA, FDA and EPA "fundamentally flawed," adding: "The existing screen is not only letting in gnats, it's letting in bulldozers."

The GAO reports excoriated the government's monitoring of the problem. But there was general agreement—among government officials, GAO investigators and subcommittee members—with the view articulated by the new chief of USDA's Food Safety and Inspection Service, Michael Taylor: "The answer is not more testing."

"We can never test enough to satisfy this subcommittee or the public," Taylor said. "The beauty of the HACCP paradigm is prevention."

Or, as Towns put it, the government is "closing the door after the animals have escaped."

The GAO's director of Food and Agriculture Issues, John Harman, testified before the subcommittee on the

two reports Towns had ordered. The first report is entitled *USDA's Role Under the National Residue Program Should Be Reevaluated*; the other examines the overall federal structure and is called *Changes Needed to Minimize Unsafe Chemicals in Food*.

Although Harman told the panel that he believes microbial contamination is a more serious problem, chemical and other contamination still warrant considerable concern, he said.

The problem was illustrated by 110 million boxes of Cheerios contaminated with an unapproved pesticide that went undetected by the government or General Mills for a year. The pesticide was not harmful at the concentrations found in the cereal.

"It was basically luck that we found this at all," concluded GAO Assistant Director of Food and Agriculture Issues Ed Zadzura.

"We have identified five basic weaknesses in the structure and systems for monitoring chemicals in food," Harman told the panel.

"First, fragmentation of responsibility among multiple

(Continued on page 3)

The Federal Monitoring System

	Chemical of concern		
	Pesticide residues	Animal drug residues	Environmental contaminants
Chemical may occur in	All foods—raw and processed, imported and domestic—and in drinking water	Meat, poultry, eggs, seafood, and dairy products, both imported and domestic	All foods—raw and processed, imported and domestic—and in drinking water
Principal laws	Federal Insecticide, Fungicide, and Rodenticide Act; Federal Food, Drug, and Cosmetic Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Egg Products Inspection Act; Pesticide Monitoring Improvements Act	Federal Food, Drug, and Cosmetics Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Egg Products Inspection Act	Federal Food, Drug, and Cosmetics Act; Federal Insecticide, Fungicide, and Rodenticide Act; Toxic Substances Control Act; Clean Water Act; Federal Meat Inspection Act; Poultry Products Inspection Act; Safe Drinking Water Act
Pre-market approval required for use on food?	Yes	Yes	No
Agency responsible for setting tolerances or standards	Environmental Protection Agency	Food and Drug Administration	Food and Drug Administration for food and the Environmental Protection Agency for water quality
Agency responsible for testing food for chemicals	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods	Department of Agriculture for meat, poultry, and egg products; Food and Drug Administration for all other foods
Agency with enforcement authority to ensure proper use of chemicals	Environmental Protection Agency in cooperation with state agencies	Food and Drug Administration in cooperation with state agencies	Environmental Protection Agency

Source: GAO

Kawai said he is confident the new drink will sell well and plans to import 4.3 million bottles from China.

Harman's aide, Zadjura, fleshed out these numbers for the subcommittee: "Most of these [383 of the 21,000-plus] were warning letters. Only one company was prosecuted and there's clearly a problem with repeat offenders," Zadjura said. "Clearly sending warning letters is

Harman also suggested that Congress "consider the feasibility of re-

Before changing the organization, Taylor added, Congress must first decide how much freedom from risk it wants—and how much it is willing to pay for that freedom.

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ATF Scrutinizes New Wine Technology

By Ian Jones

The Bureau of Alcohol, Tobacco and Firearms called Friday for public comment on four new technologies for use in winemaking.

Members of the wine industry have petitioned ATF for approval of three wine-treating processes and one wine-treating material used to reduce alcohol content, flavors, carbonation or acidity during the winemaking process.

The "spinning cone" column (SCC) process is a gas-liquid system of stationary and rotary cones which can remove off flavors in wine such as volatile acidity, ethyl acetate, hydrogen sulfide and the like, as well as reduce ethyl alcohol content.

In the making of low-alcohol wine, for instance, the first run through the spinning cone column siphons off the flavor essence of the wine, and the second reduces the alcohol content to the desired level. The essence is then added back to the wine with lowered alcohol, thus retaining its original flavor, the petitioners told ATF. The remaining alcohol can be used in other processes or destroyed.

"Treatment of wine utilizing the SCC to remove off flavors, or to reduce the alcohol content of the wine, may not alter the vinous character of the wine," ATF said in Friday's *Federal Register* notice. "Otherwise the wine would no longer be considered standard wine."

The agency added that SCC is considered a distilling process, so it may

(Continued on page 4)

GAO Snarls At FDA Animal Drug Enforcement

By John Donnelly

The Food and Drug Administration is not normally known as a toothless tiger. But General Accounting Office investigators reported last week that the FDA has compiled an abysmal record of cracking down on companies that the agency has known for years to be violators of animal drug residue regulations.

At least two of the very cases that FDA has cited to defend its track record are stories of repeated violations unhindered by federal enforcement, according to the agency's own records.

"Because the FDA lacks the authority to detain products or assess civil penalties, it cannot effectively prevent the distribution of violative products to consumers or prevent future violations from occurring," the GAO concluded in "Changes Needed to Minimize Unsafe Chemicals in Food," a report to Rep. Edolphus Towns, D-N.Y., chairman of the Human Resources and Intergovernmental Relations Subcommittee of the House Government Operations Committee.

Because FDA lacks authority to assess civil penalties, GAO said, it "must rely on the Department of Justice to follow through with criminal charges. However, criminal charges are rarely assessed because they take considerable time and significant resources to pursue."

The result is that "penalties will rarely be assessed, even in those instances when violations are detected," the report said.

From 1989 through 1992, FDA investigated 4,500 of the over 21,000 cases of violative residues in meat and poultry referred to the agency by the Food Safety and Inspection Service, the GAO reported. FDA sent warning letters in 383 of those cases and took criminal action in 15.

Only one of these cases resulted in prosecution, the GAO said.

The Clinton administration's Pathogen Reduction Act would grant the Department of Agriculture authority to impose civil penalties to enforce microbial standards for meat and poultry. And the administration's proposed Pesticide Reform Act would grant similar authorities to FDA to enforce pesticide rules.

But neither bill would stiffen FDA's ability to enforce animal drug residue violations through civil penalties.

In contrast, the GAO said, the Environmental Protection Agency assessed civil penalties in about 70 percent of the cases for which EPA, and not state agencies, took action to enforce the Federal Insecticide, Fungicide and Rodenticide Act.

(Continued on page 2)

GAO: Animal Drug Violations Go Largely Unpunished... (From page 1)

The report also said: "The Food Safety and Inspection Service reports over 4,000 illegal drug residue violations every year to FDA. However, according to a 1992 report by FDA's Extra-Label Use Task Force, because of limited resources, FDA is unable to conduct follow-up investigations on the majority of those referrals."

"In 1992, FDA and state agencies together were able to investigate only about 1,100 (or 25 percent) of USDA's referral for illegal drug residues in meat and poultry."

Responding to the GAO criticism in testimony before Rep. Towns' subcommittee last Wednesday, the director of FDA's Center for Food Safety and Applied Nutrition, Fred R. Shank, said: "It should be noted that FDA's enforcement activities with respect to animal drug residues have been significantly increased during fiscal year 1994."

"During this period, FDA initiated 11 injunctions and issued 176 warning letters in addition to conducting one evidentiary hearing under Section 305 of the Federal Food Drug and Cosmetic Act."

Shank added that the number of violative animals has decreased, from 4,339 in 1991 to 4,325 in 1992 to 3,809 in 1993. He attributed the decline to the "multiplier effect" that the publicizing of enforcement actions has in industry circles.

But the GAO's assistant director for Food and Agricultural Issues, Ed Zadajura, told the subcommittee that two of those 11 injunctions occurred only after FDA sent the alleged violators warning letters that went unheeded for years.

In one case, for many years the company did not even respond to the warning letters, ignoring them as if they were out-of-state parking tickets.

In 1993, 748 animal drugs had been approved for use on food-producing animals in the U.S., the GAO reported, and every year FDA approves

about 17 new ones. 1992 sales of animal health products were about \$2.3 billion.

Violations of the law may include using drugs not approved for food-animal use, or using them in an unapproved dose, not withholding animals that have received drugs from slaughter for a long enough period,

For many years, the company ignored FDA warning letters as if they were out-of-state parking tickets.

among others.

On Sept. 14, the U.S. District Court for the Eastern District of California at Fresno issued a consent decree of permanent injunction against the Allen Bakker Dairy. But a lot happened before then, according to FDA files reviewed by the GAO.

The first letters were sent to the firm in 1987. Three years later, in 1990, an on-site investigation led to the recommendation of a regulatory letter.

In October 1992, another on-site review found 15 violations since 1987 of irresponsible use of antibiotics. A warning letter was again recommended. In January 1993, a warning letter was sent.

In February 1993, the State of California cited the dairy for violations and USDA sent the company threatening letters in August of that year.

In February 1994, another on-site investigation found incomplete records of drugs used and evidence of extra-label drug use. An injunction was recommended after seven years of lesser threats. In March of this year the Health and Human Services and Justice Departments recommended another investigation. It was conducted in July.

Here is another story of a Northern California dairy with an even longer history of hearing FDA's saber rattle.

In January 1985, USDA found drug residues in cows sent to slaughter and threatened criminal prosecution

or injunctive action. In September 1985, FDA conducted an on-site investigation and recommended a regulatory letter, which it sent in March 1986.

The company never responded.

In August 1989, USDA sent a letter. In October 1989, came another FDA on-site inspection and another

letter. July and August 1992 saw a pair of USDA letters in the company mail box. In September 1992, the state conducted an investigation, finding 6 viola-

tions for extra-label drug use involving 10 animals in a 10 month period. The state then issued a warning letter.

In March 1993, USDA sent another letter stating violations. In April 1993, FDA was on-site again. In July 1993, the agency sent a warning letter. Violations occurred in February, March and April of 1994. In May 1994, another on-site investigation led to the recommendation of an injunction.

Food & Drink Daily was unable to determine at press time if this latter dairy was among the 11 cases FDA referred to as having been targets of injunctions.

"The FDA doesn't seek injunctions until it has sent multiple warning letters and done multiple investigations," the assistant director of the GAO's Food and Agriculture Group, Ed Zadajura, told *F&DD*.

The Department of Justice, to whom FDA refers its criminal cases, "is out chasing drug dealers and they don't have time for this," Zadajura said.

"The standard has been: unless animals are dying or human beings are becoming sick," Justice does not act.

Zadajura said he does not believe the two cases referred to above are anomalies. "I'll bet anything all 11 are at least as ugly if not worse."

Henry LaHaie, assistant director of the Department of Justice's Office of Consumer Litigation, gave a more

(Continued on page 3)

Coffee Drinkers To Face Even Higher Prices

LONDON—World prices for coffee beans have quadrupled this year, after frost and then a drought hit prospects for next year's crop in top producer Brazil, and they might go even higher.

That would soon hit drinkers of the beverage as roasters—the manufacturers of processed coffee—begin to pass on more of the cost in prices in the supermarkets.

Prices at nine-year highs of \$4,000 a metric ton for London coffee futures are not an unmixed blessing for producers, either, according to participants in talks this week of the 62-nation International Coffee Organization.

They fear that high prices might prompt extra planting and a future glut, renewing a boom-bust cycle that will play havoc with many Third World economies.

Brazil expects its 1995/96 output to fall below 15 million (60 kilogram) bags from 28 to 30 million this year and it could be even lower if the drought does not break soon.

Consumers have not yet felt the full effect. ICO delegates from consumer nations said competition among retailers and fear that people might drink tea instead had curbed retail price rises so far. But pressure will grow.

Average retail prices in Germany, the European Union's second biggest consumer after Britain, rose this summer to 9 marks (\$6) for a 500-gram (1-pound) jar from 7 marks (\$4.50).

But Hans Arno Petzold, secretary of the German Coffee Association, said that was not sufficient and a price of 10 to 11 marks (\$6.50 to \$7) would reflect the market properly.

"But even then prices need to go higher. The price rise we have had only reflects the cost of coffee bought between September 1993 and May 1994," he said.

Germans drink about 190 liters (50 gallons) of coffee a year on average.

"If the fundamental factors remain the same, with a scarcity of coffee in Brazil, so the price will remain at the present high level," Rene Montes of Guatemala said.

Other ICO delegate said the Brazilians hinted at the ICO that their 1995/96 crop could be as low as 10 million bags if sustained rainfall did not start by mid-October although an official forecast of 15.75 million bags had not changed yet.

"If Brazil does produce as low as 10 million, the price will easily hit 300 cents," said Luis Escalante, president of Costa Rica's coffee institute, ICAFE.

He was referring to New York futures for arabica coffee, now around US 215 cents per pound. London trades futures for the less expensive robusta coffee.

As higher prices risk boosting production, producers and consumers at the ICO talks consider how to avoid repetition of the boom-bust cycle that has dogged the industry for years.

Many fear that farmers will rush to plant more trees to try to take advantage of the high prices, provoking oversupply and a crash in the price in two or three years.

"Yes, it is a worry. But every country has to evaluate what is convenient for its production. What is attractive today is not necessarily good in the long term," Escalante said.

For many Latin American farmers, the temptation might be too great. It might also be difficult for Latin American governments to control farmers because coffee growing is of such social and economic importance in their countries.

In Brazil, one delegate noted, someone on the minimum salary has to work two days to buy one pound (0.45 kg) of coffee.

Delegates at the ICO have urged farmers not to increase the area they put aside for coffee growing in order to avoid a glut.

Instead, they said they hoped the high price would lead to greater productivity from current growing areas.

"I don't think the present price structure should make anyone overproduce," said Escalante. But it should encourage more efficient farming." —*Reuter*

Justice Targets The Traffickers... (From page 2)

animated defense of the enforcement of animal drug residue laws than Shank gave the subcommittee, although LaHaie said he is not an apologist for any government agency.

Justice has plenty of resources dedicated to the war on human drugs, but it is not lax in fighting misuse of animal drugs either, LaHaie said.

Like the war on controlled substances, the Office of Consumer Litigation has sought to dry up the source of unapproved drugs—the dealers, as it were. But the office has also

prosecuted for illegal use, when it discovered such actions in the course of another investigation.

"Since 1988, we have obtained the conviction of 54 individuals and eight companies for illegal receipt or distribution of unapproved drugs for food animals—or approved drugs in unapproved uses," he said.

"We have seized 60 tons of unapproved animal drugs and 10 tons of equipment, the aggregate value of which exceeds \$5 million. Some 20 individuals have gone to jail," he said,

adding: "There's more to what we have been doing from a prophylactic point of view than 11 injunctions."

Fines have exceeded \$2 million dollars, LaHaie said. And there are cases currently in the works.

"How FDA decides to send us what case is another matter," LaHaie said. "Once we receive it, we simply look at the evidence."

An FDA official who might have given a better explanation for the FDA record had not returned phone calls as of press time.



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